Cover Page
Improving Delivery of Patient-Centered Cardiac Rehabilitation
NCT02105246
August 11, 2018

Study Protocol

Background

Ischemic heart disease (IHD) is the leading cause of death in Veterans and has been identified as a priority condition for improving healthcare within the VA. Exercise-based cardiac rehabilitation (CR) is an evidence based, cost effective therapy that reduces morbidity and mortality following acute myocardial infarction (MI), coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI). The American Heart Association (AHA) and American College of Cardiology (ACC) recommend referral to CR as one of its 9 performance measures for secondary prevention (along with aspirin, beta blockers, statins and smoking cessation) in patients with IHD. Unfortunately, despite the compelling benefits and widespread endorsement of its use, CR is vastly underutilized in VHA. A recent Presidential Advisory from theAHA concluded, “The remarkably wide treatment gap between scientific evidence of the benefits of cardiac rehabilitation and clinical implementation is unacceptable.” Only 35 (27%) of VA facilities offer CR programs, and less than 10% of eligible veterans receive this guideline-recommended therapy. Geographic distance is by far the largest barrier to participation. Of the 9.2 million veterans currently enrolled in VHA, 6.7 million (73%) live more than 60 minutes from a VA CR center [based on geography data from VA Planning Systems Support Group (PSSG)]. Thus, there is an urgent need to adapt CR programs to improve access to and utilization of CR among rural veterans.

In a recent study conducted at the Iowa City VA (Wakefield et al, 2014), 48 patients completed a home-based program and 12 patients completed face-to-face CR. There was no difference in blood pressure, lipid levels, weight, glycosylated hemoglobin or rate of rehospitalization between the two groups. Home-based CR participants were highly satisfied with their care and had a better completion rate than patients who underwent face-to-face CR (89% vs. 73%). Costs for home and center-based CR programs were comparable. These findings suggest that a home-based CR program is a viable, safe, and cost- effective alternative to center based programs. In a 2010 Cochrane review, there was no significant difference in mortality among patients randomly assigned to home-based CR vs. center-based CR.

Objectives

Test the hypothesis that patients undergoing home based cardiac rehabilitation will not differ in 6 minute walk time, physical activity, quality of life, patient and caregiver satisfaction, and re-hospitalization as compared with patients undergoing center-based cardiac rehabilitation.

Aim 1. Determine whether automatic referral to home- vs. center-based CR increases patient participation in CR after hospitalization for myocardial infarction or coronary revascularization.
Aim 2. Among patients who choose to participate in CR, compare the effectiveness of home- vs. center-based CR on six-minute walk distance, quality of life, and healthcare expenditures.
Aim 3: Determine whether the effects of home vs. center-based CR differ by age, gender, race, ethnicity, distance from medical center, employment, socioeconomic status, social support, caregiver status, comorbid conditions, or patient preference.

Study Design

Cardiac rehabilitation involves exercise training, education, and lifestyle counseling for patients with cardiac conditions. Home and center-based cardiac rehabilitation programs, if followed by patients, are equally effective in their benefits on risk factors, health-related quality of life, death, and clinical events following acute myocardial infarction or coronary revascularization. This study will compare the effectiveness of existing cardiac rehabilitation programs. The San Francisco VA Medical center offers a home-based (but not a center based) cardiac rehabilitation program to patients who are hospitalized for myocardial infarction, percutaneous coronary intervention, or coronary artery bypass grafting. The other study sites offer a center-based (but not a home-based) cardiac rehabilitation to the same group of patients. All facilities have initiated a comprehensive CR intervention with 7 components:

1. Educate and engage stakeholders (grand rounds, posters, brochures, one-on-one meetings)
2. Automate referrals

3. Standardize templates and stop codes for consults, progress notes, exercise prescription, and the patients' Individualized Treatment Plans
4. Use database to track all patients referred; monitor % enrolled, number of sessions completed.
5. Standardize outcome assessment
6. For CABG patients, provide in-hospital assessment and phase I cardiac rehabilitation; coordinate care with home PT
7. Offer a phase II cardiac rehabilitation program within 6 months of hospitalization.

The only difference between the sites is that San Francisco offers a home-based cardiac rehab program and other sites will offer a center-based cardiac rehab program. Research outcomes will include processes of care (% of eligible patients referred, % enrolled, average number of sessions completed, provider knowledge) and patient outcomes (6 minute walk distance, physical activity, quality of life, patient and caregiver satisfaction, rehospitalization, mortality). The study will evaluate the effectiveness of each CR program on these outcomes. In addition, research participants will be asked to participate in a total of 3 additional study visits. The visits will take place 3 months, 6 months, and 12 months after their enrollment in the cardiac rehabilitation program. Medical records will be reviewed and death certificates will be obtained for up to 10 years of follow-up.

Statistical Analysis Plan

The outcomes listed will be measured at baseline, and then at 3, 6, and 12 months following first visit to CR. Prior to inferential statistics, we will use descriptive statistics and graphs to explore distributions, univariate outliers, and basic bivariate associations with home- vs. center-based CR. We will then compare baseline characteristics of the two groups to examine differences on key subgroup variables including age and type of procedure resulting in the need for CR. Imbalanced baseline measures will be included as covariates in outcome analyses. To appropriately model these nested data, we will use linear mixed models also called multilevel or hierarchical linear models. Our primary outcomes on which only the patient or their caregiver provide data will be analyzed using a multivariate regression model with a simple random -effects structure with repeated-measures. We anticipate that patients who agree to enroll in home-based CR will be different than those who agree to enroll in center- based CR. Therefore, we will use other variables measured at baseline to construct a propensity score for home- vs. center-based CR, and we will adjust the multivariable analyses for this propensity score. Planned subgroup analyses will include the effects of the following predictors on outcomes: age, gender, race/ethnicity, SES, distance to nearest facility that can provide rehabilitation, and presence of caregivers. We will determine whether these same socio-demographic factors are associated with patient preference. We will also conduct subgroup analyses where we have identical measures from patients and caregivers.

Study Application (Version 1.14)

1.0 General Information

***Enter the full title of your study:**

Improving Delivery of Patient-Centered Cardiac Rehabilitation

***Enter the study number or study alias**

Improving Delivery of Patient-Centered Cardiac Rehabilitation
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List departments and/or research programs associated with this study:

Primary Dept?	Department Name
◉	**UCSF** - *138331* - M_MED-VAMC-ADMIN

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Mary A Whooley

Select if applicable

☐ Department Chair ☐ Resident

☐ Fellow

If the Principal Investigator is a Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Redberg, Rita F
Other Investigator
Schopfer, David, MD
Other Investigator

B) Research Support Staff

Ahi, Tara
Study Coordinator
Bettencourt, Michael
Study Recruiter

Hay, Kristen
Research Assistant
Lee, Rado
Study Coordinator
Munson, Scott
Research Assistant
Piros, Kimberly
Study Nurse
Williams, Katherine PhD
Study Coordinator

3.3 *Please add a Study Contact:

Ahi, Tara
Munson, Scott
Whooley, Mary A
Williams, Katherine PhD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor/Mentor:

3.5 If applicable, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

4.0 Qualifications of Key Study Personnel

4.1 November, 2015 - NEW Definition of Key Study Personnel and CITI Training Requirements:

UCSF Key Study Personnel include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of the research. Key Personnel also include faculty mentors/advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application. **The IRB requires that all Key Study Personnel complete Human Subjects Protection Training through CITI prior to approval of a new study, or a modification in which KSP are being added. More information on the CITI training requirement can be found on our website.**

List the study responsibilities and qualifications of any individuals who qualify as Key Study Personnel (KSP) at UCSF and affiliated sites ONLY by clicking the "Add a new row" button. This information is required and your application will be considered incomplete without it.

KSP Name	Description of Study Responsibilities	Qualifications
Whooley, Mary A	Principal Investigator	Dr. Whooley is a professor in the Department of Medicine at UCSF and an attending physician at the San Francisco VA Medical Center.

Schopfer, David, MD	Co-investigator	Dr. Schopfer is a cardiologist with experience working on a number of cardiology studies at the San Francisco VA Medical Center.
Piros, Kimberly	Study Nurse	Kimberly Piros is a registered nurse who has extensive experience working with patients at the San Francisco VA Medical Center. He is the primary nurse provider associated with the VA's Healthy Heart Program.
Pabst, Mark S	Project Coordinator/Manager	Mark Pabst has ten years experience managing clinical research studies at UCSF and the San Francisco VA Medical Center.
Munson, Scott	Research Assistant	Scott Munson has worked on Dr. Whooley's research projects for over five years and has superior knowledge of UCSF and VA research regulations.
Redberg, Rita F	Co-investigator	Dr. Redberg is a cardiologist with expertise in the effects of exercise on cardiovascular disease.
Ahi, Tara	Clinical research coordinator	Tara Ahi is a UCSF Clinical Research Coordinator Asst at the SFVAMC.
Bettencourt, Michael	Study Recruiter	Michael Bettencourt is an exercise physiologist who works closely with the subjects in this study and will be responsible for recruiting subjects into the study.
Hay, Kristen	Research Assistant	Kristen Hay has extensive experience working with patients at the SFVAMC. She is currently working with the Million Veterans Program while assisting with the Healthy Heart Program as well.
Lee, Rado	Study coordinator	Rado Lee has extensive experience in tracking expenses and coordinating study efforts

5.0 Initial Screening Questions - Updated 9/13

(Note: You must answer every question on this page to proceed).
If you are converting to the new form, check questions 5.4, 5.6, 5.7, 5.8 and 5.10 before saving and continuing to the next section.

5.1 * Application type:

- (•) Full Committee
- ( ) Expedited
- ( ) Exempt

5.2 * Risk level (Help Text updated 9/13):

- (•) Minimal risk
- ( ) Greater than minimal risk

5.3 * Subject contact:

- (•) Yes (including phone, email or web contact)
- ( ) No (limited to medical records review, biological specimen analysis, and/or data analysis)

5.4 * Funding (past or present):

- (•) Funded or will be funded (external sponsor, gift, program or specific internal or departmental funds)
- ( ) Unfunded (no specific funds earmarked for this project)
- ( ) Unfunded student project

5.5 * The Principal Investigator and/or one or more of the key study personnel has financial interests related to this study:

( ) Yes (•) No

If **Yes**, the Conflict of Interest Advisory Committee (COIAC) office may contact you for additional information.

5.6 * This is an investigator-initiated study:

(•) Yes ( ) No

5.7 * This study ONLY involves retrospective records review and/or identifiable biospecimen analysis:

( ) Yes (•) No

5.8 * This is a clinical trial:

(•) Yes ( ) No

Clinical Trial Registration
"NCT" number for this trial:

NCT02105246

5.9 * This is a multicenter study:

(•) Yes ( ) No

5.10 * This application involves the study of unapproved or approved drugs, devices, biologics or in vitro

diagnostics:

○ Yes ◉ No

5.11 * This application involves a Humanitarian Use Device:

◉ No
○ Yes, and it includes a research component
○ Yes, and it involves clinical care ONLY

5.12 * This study involves human stem cells (including iPS cells and adult stem cells), gametes or embryos:

◉ No
○ Yes, and requires CHR and GESCR review
○ Yes, and requires GESCR review, but NOT CHR review

5.13 * This is a CIRB study (e.g. the NCI CIRB will be the IRB of record):

○ Yes ◉ No

5.14 * This application includes a request to rely on another IRB (other than NCI CIRB):

○ Yes ◉ No

Note: If this request is approved, the CHR will **NOT** review and approve this study. Another institution will be the IRB of record.

6.0 Funding

6.1 Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor: **Note: we require only a P Number *OR* an A Number for funding coming through UCSF. Please avoid these common errors in funding documentation:**

- **DO NOT add the A Number if a P Number was already provided OR update the A Number field when a new funding cycle begins. The IRB does NOT use this information or want these changes made.**
- **DO NOT add a grant continuation as a new funding source.**

External Sponsor:

View Details	Sponsor Name	Sponsor Type	Awardee Institution	Contract Type:	UCSF RAS "P number" or eProposal number	UCSF RAS System Award Number ("A" + 6 digits)
⊟	Patient-Centered Outcomes Research Inst	05	UCSF		P0058380	

Sponsor Name:	Patient-Centered Outcomes Research Inst
Sponsor Type:	05
Sponsor Role:	Funding
Grant/Contract Number:	
Awardee Institution:	UCSF
Is Institution the Primary Grant Holder:	Yes
Contract Type:	
UCSF RAS "P number" or eProposal number:	P0058380
UCSF RAS System Award Number ("A" + 6 digits):	
Grant Number for Studies Not Funded thru UCSF:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	
Significant Discrepancy:	

Gift, Program, or Internal Funding (check all that apply):

- ☐ Funded by gift (specify source below)
- ☐ Funded by UCSF or UC-wide program (specify source below)
- ☐ Specific departmental funding (specify source below, if applicable)

List the gift, program, or departmental funding source:

6.2 If you tried to add a sponsor in the question above and it was not in the list, follow these steps:

- **If funding has already been awarded or the contract is being processed by the Office of Sponsored Research (OSR) or Industry Contracts Division (ICD), your sponsor is already in the system and the project has an eProposal Proposal or Award number. Check with your department's OSR Staff or ICD Officer to ask how the sponsor is listed in the UC sponsor list and what the Proposal or Award number is. Click here to find your OSR staff and here to find your ICD staff.**
- **If your sponsor is not yet in the list, enter it in the box below.**

○ Sponsor not in list

Only if your sponsor is not yet in the list, type the sponsor's name:

If the funding is administered by the UCSF Office of Sponsored Research, your study will not receive CHR approval until the sponsor and funding details have been added to your application.

6.3 * This study is currently supported in whole or in part by Federal funding OR has received ANY Federal funding in the past (Help Text updated 9/13):

○ Yes ◉ No

If **yes**, indicate which portion of your grant you will be attaching:

- [ ] The Research Plan, including the Human Subjects Section of your NIH grant or subcontract
- [ ] For other federal proposals (contracts or grants), the section of the proposal describing human subjects work
- [ ] The section of your progress report if it provides the most current information about your human subjects work
- [ ] The grant is not attached. The study is funded by an award that does not describe specific plans for human subjects, such as career development awards (K awards), cooperative agreements, program projects, and training grants (T32 awards) OR UCSF (or the affiliate institution) is not the prime recipient of the award

7.0 Sites

7.1 Institutions (check all that apply):

- [x] UCSF
- [ ] China Basin
- [ ] Helen Diller Family Comprehensive Cancer Center
- [ ] Mission Bay
- [ ] Mount Zion
- [ ] San Francisco General Hospital (SFGH)
- [x] SF VA Medical Center (SF VAMC)
- [ ] Blood Centers of the Pacific (BCP)
- [ ] Blood Systems Research Institute (BSRI)
- [ ] Fresno (Community Medical Center)
- [ ] Gallo
- [ ] Gladstone
- [ ] Institute on Aging (IOA)
- [ ] Jewish Home
- [ ] SF Dept of Public Health (DPH)

7.2 Check all the other types of sites not affiliated with UCSF with which you are cooperating or collaborating on this project (Help Text updated 9/13):

- [ ] Other UC Campus
- [x] Other institution
- [ ] Other community-based site
- [ ] Foreign Country

List the foreign country/ies:

7.3 Check any research programs this study is associated with:

- [ ] Cancer Center
- [ ] Center for AIDS Prevention Sciences (CAPS)
- [ ] Global Health Sciences
- [ ] Immune Tolerance Network (ITN)
- [ ] Neurosciences Clinical Research Unit (NCRU)
- [ ] Osher Center
- [ ] Positive Health Program

8.0 Studies Involving Other Sites

8.1 UCSF is the coordinating center:

(•) Yes ( ) No

If **Yes**, describe the plan for communicating safety updates, interim results, and other information that may impact risks to the subject or others among sites:

Important information, including safety updates and interim results, will be communicated to other sites by means of study memorandae (SM). Study memorandae will be numbered sequentially in the order in which they are issued and a complete list will be stored at the coordinating center. Each of these documents will be prepared by coordinating center personnel, signed by the coordinating center's principal investigator, and then sent by email to the principal investigator and main study contact at each study satellite site.

If **Yes**, describe the plan for sharing modification(s) to the protocol or consent document(s) among sites:

All modifications to protocol and consent documentation will be communicated through the distribution of study memorandae to principal investigators and main study contacts at each study site. These documents will detail the exact changes made to protocol and consent documents, including specific change to language in the protocol and/or consent.

8.2 Check any other UC campuses with which you are collaborating on this research study:

- [ ] UC Berkeley
- [ ] UC Davis
- [ ] Lawrence Berkeley National Laboratory (LBNL)
- [ ] UC Irvine
- [ ] UC Los Angeles
- [ ] UC Merced
- [ ] UC Riverside
- [ ] UC San Diego
- [ ] UC Santa Barbara
- [ ] UC Santa Cruz

8.3 Are the above UC campuses requesting to rely on UCSF's IRB (check all that apply):

- [ ] Yes (Submit a reliance request through the UC IRB Reliance Registry)
- [ ] No (Complete IRB Approval Certification section)

9.0 Outside Site Information

9.1 Outside Site Information

Click "Add a new row" to enter information for a site. Click it again to add a second site again to add a third site, a fourth site, etc.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

VA Ann Arbor Healthcare System

Contact name:

Claire Duvernoy

Email:

duvernoy@med.umich.edu

Phone:

(734) 936-7507

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- (•) The non-affiliated site's IRB or a private IRB
- ( ) The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ( ) The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Pittsburg VA Healthcare System

Contact name:

Dan Forman

Email:

DEFORMAN@PARTNERS.ORG

Phone:

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- (●) The non-affiliated site's IRB or a private IRB
- ( ) The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ( ) The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

10.0 Study Design

10.1 * Study design (Help Text updated 9/13):

Cardiac rehabilitation involves exercise training, education, and lifestyle counseling for patients with cardiac conditions. Home and center-based cardiac rehabilitation programs, if followed by patients, are equally effective in their benefits on risk factors, health-related quality of life, death, and clinical events following acute myocardial infarction or coronary revascularization. This study will compare the effectiveness of existing cardiac rehabilitation programs. The San Francisco VA Medical center offers a home-based (but not a center-based) cardiac rehabilitation program to patients who are hospitalized for myocardial infarction, percutaneous coronary intervention, or coronary artery bypass grafting. The other study sites offer a center-based (but not a home-based) cardiac rehabilitation to the same group of patients. All facilities have initiated a comprehensive CR intervention with 7 components:

1. Educate and engage stakeholders (grand rounds, posters, brochures, one-on-one meetings)

1. Automate referrals

1. Standardize templates and stop codes for consults, progress notes, exercise prescription, and the patients' Individualized Treatment Plans

1. Use database to track all patients referred; monitor % enrolled, number of sessions completed.

1. Standardize outcome assessment

1. For CABG patients, provide in-hospital assessment and phase I cardiac rehabilitation; coordinate care with home PT

1. Offer a phase II cardiac rehabilitation program within 6 months of hospitalization.

The only difference between the sites is that San Francisco offers a home-based cardiac rehab program and other sites will offer a center-based cardiac rehab program.

Research outcomes will include processes of care (% of eligible patients referred, % enrolled, average number of sessions completed, provider knowledge) and patient outcomes (6 minute walk distance, physical activity, quality of life, patient and caregiver satisfaction, re-hospitalization, mortality). The study will evaluate the effectiveness of each CR program on these outcomes. All 6 minute walk tests associated with the home-based portion of the study will be conducted at the San Francisco VA Medical Center.

In addition, research participants will be asked to participate in a total of 2 additional study visits. The visits will take place 3 months and 6 months after their enrollment in the cardiac rehabilitation program. Medical records will be reviewed and death certificates will be obtained for up to 10 years of follow-up. T his protocol will require national access to VA electronic health records through CAPRI and/or VistAWeb.

10.2 If this is a clinical trial, check the applicable phase(s) (Help Text updated 9/13):

- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV

11.0 Scientific Considerations

11.1 Hypothesis (Help Text updated 9/13):

This study has a hypothesis:

◉ Yes ○ No

If yes, state the hypothesis or hypotheses:

Patients undergoing home based cardiac rehabilitation will not differ in 6 minute walk time, physical activity, quality of life, patient and caregiver satisfaction, and re-hospitalization as compared with patients undergoing center-based cardiac rehabilitation.

11.2 * List the specific aims:

Aim 1. Determine whether automatic referral to home- vs. center-based CR increases patient participation in CR after hospitalization for myocardial infarction or coronary revascularization.

Aim 2. Among patients who choose to participate in CR, compare the effectiveness of home- vs. center-based CR on six-minute walk distance, quality of life, and healthcare expenditures.

Aim 3: Determine whether the effects of home vs. center-based CR differ by age, gender, race, ethnicity, distance from medical center, employment, socioeconomic status, social support, caregiver status, comorbid conditions, or patient preference.

11.3 Statistical analysis:

The outcomes listed will be measured at baseline, and then at 3 and 6 months following first visit to CR. Prior to inferential statistics, we will use descriptive statistics and graphs to explore distributions, univariate outliers, and basic bivariate associations with home- vs. center-based CR. We will then compare baseline characteristics of the two groups to examine differences on key subgroup variables including age and type of procedure resulting in the need for CR. Imbalanced baseline measures will be included as covariates in outcome analyses.

To appropriately model these nested data, we will use linear mixed models also called multilevel or hierarchical linear models. Our primary outcomes on which only the patient or their caregiver provide data will be analyzed using a multivariate regression model with a simple random -effects structure with repeated-measures. We anticipate that patients who agree to enroll in home-based CR will be different than those who agree to enroll in center- based CR. Therefore, we will use other variables measured at baseline to construct a propensity score for home- vs. center-based CR, and we will adjust the multivariable analyses for this propensity score. Planned subgroup analyses will include the effects of the following predictors on outcomes: age, gender, race/ethnicity, SES, distance to nearest facility that can provide rehabilitation, and presence of caregivers. We will determine whether these same socio-demographic factors are associated with patient preference. We will also conduct subgroup analyses where we have identical measures from patients and caregivers.

11.4 If this study has undergone scientific or scholarly review, please indicate which entity performed the review:

- ☐ Cancer Center Protocol Review Committee (PRC) (Full approval is required prior to final CHR approval for cancer-related protocols.)
- ☐ CTSI Clinical Research Center (CRC) advisory committee
- ☐ Departmental scientific review
- ☐ Other:

Specify **Other**:

12.0 Background

12.1 Background:

Ischemic heart disease (IHD) is the leading cause of death in Veterans and has been identified as a priority condition for improving healthcare within the VA. Exercise-based cardiac rehabilitation (CR) is an evidence-based, cost effective therapy that reduces morbidity and mortality following acute myocardial infarction (MI), coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI). The American Heart Association (AHA) and American College of Cardiology (ACC) recommend referral to CR as one of its 9 performance measures for secondary prevention (along with aspirin, beta blockers, statins and smoking cessation) in patients with IHD. Unfortunately, despite the compelling benefits and widespread endorsement of its use, CR is vastly underutilized in VHA. A recent Presidential Advisory from theAHA concluded, "The remarkably wide treatment gap between scientific evidence of the benefits of cardiac rehabilitation and clinical implementation is unacceptable." Only 35 (27%) of VA facilities offer CR programs, and less than 10% of eligible veterans receive this guideline-recommended therapy. Geographic distance is by far the largest barrier to participation. Of the 9.2 million veterans currently enrolled in VHA, 6.7 million (73%) live more than 60 minutes from a VA CR center [based on geography data from VA Planning Systems Support Group (PSSG)]. Thus, there is an urgent need to adapt CR programs to improve access to and utilization of CR among rural veterans.

12.2 Preliminary studies:

In a recent study conducted at the Iowa City VA (Wakefield et al, 2014), 48 patients completed a home-based program and 12 patients completed face-to-face CR. There was no difference in blood pressure, lipid levels, weight, glycosylated hemoglobin or rate of rehospitalization between the two groups. Home-based CR participants were highly satisfied with their care and had a better completion rate than patients who underwent face-to-face CR (89% vs. 73%). Costs for home and center-based CR programs were comparable. These findings suggest that a home-based CR program is a viable, safe, and cost- effective alternative to center-based programs. In a 2010 Cochrane review, there was no significant difference in mortality among patients randomly assigned to home-based CR vs. center-based CR.

12.3 References:

If you have a separate bibliography, attach it to the submission with your other study documents.

13.0 Sample Size and Eligibility

13.1 Number of subjects that will be enrolled at UCSF and affiliated institutions:

200

13.2 Total number of subjects that will be enrolled at all sites (Help Text updated 9/13):

400

13.3 Estimated number of people that you will need to consent and screen here (but not necessarily enroll) to get the needed subjects:

400

13.4 Explain how and why the number of subjects was chosen (Help Text updated 9/13):

Sample size estimation for the difference between two groups over four assessments assuming a linear trend. The estimate is based on a two-sided alpha of .05, power of .90, a constant correlation of 0.5 among all repeated measurements, and a 5% overall attrition. San Francisco will enroll 200 participants while the other centers will enroll 100 participants each with a study total of 400 participants. With these assumptions, a composite effect of .5 can be detected

13.5 * Eligible age range(s):

- [ ] 0-6 years
- [ ] 7-12 years
- [ ] 13-17 years
- [x] 18+ years

13.6 Inclusion criteria:

- CABG within 6 months prior to first session
- PCI within 6 months prior to first session
- Acute MI within 6 months prior to first session

13.7 Exclusion criteria:

- Age < 18 years
- Pregnant
- Behavioral or cognitive limitations that interfere with performing exercise training
- Significant movement disorder that interferes with exercise training
- Blind, deaf or mute
- Homeless (or unstable housing anticipated during the next 3 months)
- LVEF <35% without ICD
- Staged PCI with significant remaining lesion
- Decompensated heart failure
- QTc > 500 msec and no ICD
- 6MWT < 75 m (post-op) or < 150 m (non-surgical)
- Long-term (>30 days) SNF placement
- Atrial arrhythmia not rate controlled
- Mobitz Type II or 3rd degree AV block without pacemaker
- Deceased
- History of unprovoked or exercise-induced VT, VF or syncope with no ICD
- Concerning ventricular ectopy in past 24 hours with no ICD (Lown grading system)
    - Polymorphic/multiform PVCs
    - Couplets, Salvos, or non-sustained VT
    - R on T pattern
    - >10 PVCs per minute

13.8 There are inclusion or exclusion criteria based on gender, race or ethnicity:

○ Yes ◉ No

If **yes**, please explain the nature and rationale for the restrictions:

14.0 Other Approvals and Registrations

14.1 * Do any study activities take place on patient care units:

○ Yes ◉ No

If **Yes**, attach a letter of support for the study from the involved patient care manager(s).

14.2 * Does your protocol involve any radiation exposure to patients/subjects? The UCSF Radiation Safety Committee requires review of your protocol if it includes administration of radiation as part of standard of care OR research exposures:

○ Yes ◉ No

14.3 * This study may generate genetic data that may be broadly shared (e.g. submitted to NIH for Genome-Wide Association Studies (GWAS) in dbGaP, TCGA, etc):

○ Yes ◉ No

14.4 * This study involves administration of vaccines produced using recombinant DNA technologies to human subjects:

○ Yes ◉ No

14.5 * This study involves human gene transfer (NOTE: Requires NIH Recombinant DNA Advisory Committee (RAC) review prior to CHR approval):

○ Yes ◉ No

14.6 This study involves other regulated materials and requires approval and/or authorization from the following regulatory committees:

☐ Institutional Biological Safety Committee (IBC)

Specify BUA #:

☐ Institutional Animal Care and Use Committee (IACUC)

Specify IACUC #:

☐ Radiation Safety Committee

Specify RUA #:

☐ Radioactive Drug Research Committee (RDRC)

Specify RDRC #:

☐ Controlled Substances

15.0 Procedures

15.1 * Procedures/Methods (Help Text updated 9/13) For clinical research list all study procedures, test and treatments required for this study, including when and how often they will be performed. If there are no clinical procedures, describe the Methods:

The following table lists measurements that will be collected as part of usual care (whether or not the patient participates in the study). This includes information collected from both medical records and subject interview, and the timepoint at which the information is collected. This protocol will require national access to VA electronic health records through CAPRI and/or VistAWebInformation will not be used or stored from subjects who withdraw or are withdrawn from the study.

Clinical (Standard of Care) Measurements	**Baseline**	**12 weeks**	**6 months**
Date	X	X	X
Resting blood pressure (mm Hg)	X	X	X
Resting pulse (beats/min)	X	X	X
Weight (kg, lbs)	X	X	X
Resting O2 sat	X	X	X
Height (cm, in)	X		
Waist circumference (cm)	X		
Hip circumference (cm)	X		
Steps per week	X	X	X
6MWT standardized course			
Date	X		
Start time (_ _ : _ _)	X		
End time (_ _ : _ _)	X		
Total distance (meters? feet?)	X		
Peak heart rate	X		
O2 sat at end of course	X		
Max perceived exertion (Borg 1- 10)	X		
Comments	X		

	Baseline	12 Weeks	6months
Medication use			
Aspirin	X	X	X
Clopidogrel	X	X	X
Beta blocker	X	X	X
Angiotensin receptor blocker (ACE/ARB)	X	X	X
Calcium channel blocker	X	X	X
Statin	X	X	X
Niacin	X	X	X
Fish oil	X	X	X
Other cholesterol medication	X	X	X
Diuretic	X	X	X
Nitrate	X	X	X
Insulin	X	X	X
Oral hypoglycemic (e.g., metformin, glipizide)	X	X	X
Warfarin	X	X	X
Factor Xa inhibitor (e.g., Rivaroxaban, Apixaban)	X	X	X
Proton pump inhibitor (e.g., omeprazole, pantoprazole)			
Other?	X	X	X
Labs			
Lipid panel (HDL, total chol, triglyceride, calculated LDL)	X	X	X

Direct LDL	X		X
Complete blood count (CBC)	X		X
Liver function tests	X		X
Albumin	X		X
Urine microalbumin	X		X
Urine creatinine	X		X
Electrolytes (Na, K, Cl, C02)	X		X
Glucose	X		X
BUN	X	X	X
Hemoglobin A1C	X	X	X
Creatinine	X	X	X
eGFR (calculated)	X	X	X
B-type natriuretic peptide (BNP)	X	X	X
Troponin-I	X		
High sensitivity CRP*	X		
Questionnaires			
CCS angina classification? Self-reported angina frequency?	X	X	X

Activity during the past month? Not at all active A little active (1 to 2 times/month) Fairly active (3 to 4 times/month) Quite active (1 to 2 times/week) Very active (3 to 4 times/week) Extremely active (5 or more times/week)	X	X	X
Typical week during the past month **F** requency **I** ntensity **T** ime **T** ype	X	X	X
Number of hours sitting per weekday			
Overall quality of life	X	X	X
Disease-specific quality of life	X	X	X
Depressive symptoms	X	X	X
Anxiety symptoms	X	X	X
Positive affect	X	X	X
Servings fruits/vegetables per day	X	X	X
Smoking	X	X	X
Alcohol use	X	X	X
Drug use	X	X	X
Comorbid medical conditions	X	X	X

The following table lists all information collected from study subjects for research only. This includes information collected from subject interviews, questionnaires, and other research activities (i.e. the six minute walk test conducted at months 3 and 6). The table also includes the timepoint at which the information is collected.

Research Measurements	**Baseline**	**12 weeks**	**6 months**
6MWT standardized course			
Date	SOC	X	X
Start time (_ _ : _ _)	SOC	X	X
End time (_ _ : _ _)	SOC	X	X
Total distance (meters? feet?)	SOC	X	X
Peak heart rate	SOC	X	X
O2 sat at end of course	SOC	X	X
Max perceived exertion (Borg 1-10)	SOC	X	X
Comments	SOC	X	X
Trails A and B (seconds to complete)	X	X	X
Digit symbol (# correct in 120 sec)	X		X
Number of chair stands in 30 sec	X		X
Overall quality of life	X	X	X
Disease-specific quality of life	X	X	X

Satisfaction with health care	X		X		X							
Sleep quality	X		X		X							
Positive affect	X		X		X							
Caregiver communication	X		X		X							
Functional status (ADLs, IADLs)	X		X		X							
Cardiac self-efficacy	X		X		X							
Exercise self-efficacy	X		X		X							
Patient Activiation	X		X		X							
Rate My Plate	X		X		X							
Servings fruits/vegetables per day	X		X		X							
Grams of saturated fat per day	X		X		X							
Medication adherance	X		X		X							
Smoking	X		X		X							
Other Outcomes												
Days until resume driving			X									
Days until resume intercourse			X									
Days until resume work			X									
Patient (out of pocket) expenses			X									
Knowledge about cardiac disease	X		X		X							
Days until rehospitalization	X			X		X						
Reason for rehospitalization	X		X		X							
Days until death	X		X		X							
Cause of death	X		X		X							
Tandem Stand Test		X			X			X				
Side by side Stand Test		X			X			X				
Heel Toe Stand Test		X			X			X				

If you have a procedure table, attach it to the submission with your other study documents.

15.2 Interviews, questionnaires, and/or surveys will be administered or focus groups will be conducted:

(•) Yes ( ) No

List any standard instruments used for this study:

Trails A and B coginitive function tests
Digit symbol cognitive function test
Seattle Angina Questionnaire
Patient Activation Measure
International Physical Activity Questionnaire
Index of Activities of Daily Living
Dietary Assessment Medication Adherence
Perceived Stress
Patient Satisfaction in Healthcare
AUDIT
REAP
MOCA
PHQ 8
DASI

Attach any non-standard instruments at the end of the application.

15.3 Conduct of study procedures or tests off-site by non-UCSF personnel:

○ Yes ◉ No

If yes, explain:

15.4 Sharing of experimental research test results with subjects or their care providers:

○ Yes ◉ No

If yes, explain:

15.5 * Specimen collection for future research and/or specimen repository/bank administration:

○ Yes ◉ No

15.6 Time commitment (per visit and in total):

Baseline visit will include an additional 1 hour of research related activity
Month 3 and Month 6 follow up visits will take approximately 1 hour and 30 minutes for research activities.
Total time committment will be approximately 4 hours over 6 months.

15.7 Locations:

All study activities and data collection will take place either by telephone or at the San Francisco VA Medical center. All telephone calls to collect data will originate from the SFVAMC.

15.8 Describe the resources in place to conduct this study in a way that assures protection of the rights and welfare of participants:

We have the neccessary staff, space, and resources to complete the study. All staff have completed human subject's training as required by UCSF and the SFVAMC. The SFVAMC has on-site 24 hour emergency medical and psychiatric care should the need for these resources arise.

16.0 Alternatives

16.1 Study drug or treatment is available off-study:

○ Yes
○ No
◉ Not applicable

16.2 * Is there a standard of care (SOC) or usual care that would be offered to prospective subjects at UCSF (or the study site) if they did not participate:

◉ Yes ○ No

If yes, describe the SOC or usual care that patients would receive if they choose not to participate:

If subjects choose not to participate in this study they can continue to particpate in the standard of care cardiac rehabilitation option(s) available to them. At the San Francisco VA Medical Center these options include participating in a home-based CR program administered through the SFVAMC or referral to an outside center-based CR program.

16.3 Describe other alternatives to study participation that are available to prospective subjects:

Patients may elect to participate in cardiac rehabilitation without being part of the study or they may elect to not participate in any cardiac rehabilitation program.

17.0 Risks and Benefits

17.1 * Risks and discomforts:

Questionnaires: The questionnaires will involve personal questions. Some of the questions may make the participant uncomfortable or upset.

6 minute walk test: The risks of any exercise test include disorders of the heart beat, abnormal blood pressure responses and dizziness. However, these risks are exceedingly rare during the 6 minute walk test.

Balance tests:
Risks associated with the balance tests include abnormal blood pressure responses and dizziness and potential fall. These risks are excedingley rare

Confidentiality: Participation in research will involve a loss of privacy, but information will be handled as confidentially as possible. Names will not be used in any published reports about this study.

17.2 Steps taken to minimize risks to subjects:

Questionnaires: Participants are free to decline the questionnaires. Any subject identified to be actively suicidal at the study appointment or during a follow-up interview will receive immediate psychiatric referral, which is available 24 hours per day at the San Francisco VA medical Center.

6 minute walk test: Participants will be monitored closely while assessments are made in the hospital. Testing will be halted for chest pain or shortness of breath.

Balance tests: Study personnel will stand next to subjects when they perform the balance tests. This will allow personnel to catch study subjest should they fall. In addition, balance tests will be conducted next toa wall with attached bar that study subjects will be able to grab if they become dizzy.

Confidentiality: Names will not be used in any published reports about this study. Use of identifying information will be minimized and adhere to VA privacy guidelines for storage. (double locked file cabinets and encrypted electronic sources)

17.3 Benefits to subjects:

○ Yes ◉ No

If yes, describe:

17.4 Benefits to society:

If home based cardiac rehabilitation is proven equitable to center based cardiac rehabilitation, the costs associated with care could be lower and the overall incidence of repeated revascularization could be

lower. The travel burden related to center based cardiac rehabilitation could be eliminated. Patient satisfaction and quality of life may be increased in the home-based rehabilitation arm as they will not need to attend a cardiac rehabilitation clinic outside of their home.

17.5 Explain why the risks to subjects are reasonable:

If the study is successful in determining the most effective aspects of cardiac rehabilitation and determining whether home-based CR is as effective as center-based CR, future participants in CR programs may have an improved quality of life and fewer cardiac events. The risks of particpation are relatively minimal to the individual, with potential benefits to society outweighing these risks.

18.0 Data and Safety Monitoring Plan

18.1 Describe the plan for monitoring data and safety (Help Text updated 9/13):

Study staff will keep active and regular surveillance of the vital status of all subjects enrolled in this research study and report any and all adverse events as they occur. Study nurses will conduct an extensive initial assessment of all study subjects to determine any exercise risk factors and will maintain regular contact with subjects throughout their participation in the study. Serious adverse events that meet the reporting requirements set out by the UCSF Committee on Human Research will be reported within five working days of awareness.

18.2 This study requires a Data and Safety Monitoring Board:

- ○ Yes
- ◉ No or not sure

If **yes**, press **SAVE and CONTINUE** to move to the next section of the application.

18.3 If No, provide rationale:

- ○ Social/Behavioral research
- ○ Phase I trial
- ○ Treatment IND/Compassionate Use Trial
- ◉ Other (explain below)

If **Other,** explain:

Because this study does not include a control group, it will be difficult for a data safety monitoring board to determine whether any adverse events are due to study activities. As a result, we will not convene a DSMB to monitor this study.

19.0 Confidentiality and Privacy

19.1 Plans for maintaining privacy in the research setting:

Participant data will be maintained per VA Privacy Protocols. Paper consents will be stored in double locked cabinets. Electronic data will be on encrypted drive. Use of identifying information will be minimized. Phone calls will not be recorded and caregivers who may be involved in the patient's care and recipient of patient information will be identified prior to the calls with the patient's consent.

Data will not be transferred from VA entities to non-VA entities.

19.2 Possible consequences to subjects resulting from a loss of privacy:

A loss of privacy may result in divulging patient health history and lab data, participation in a clinical research study, and personal demographics including insurance status and income. Subjects who participate in this study and have their information divulged could potentially experience job loss, loss of insurance coverage, or other consequences.

19.3 Study data are:

- [ ] Derived from the Integrated Data Repository (IDR) or The Health Record Data Service (THREDS) at SFGH
- [x] Derived from a medical record (e.g. APeX, OnCore, etc. Identify source below)
- [ ] Added to the hospital or clinical medical record
- [x] Created or collected as part of health care
- [ ] Used to make health care decisions
- [x] Obtained from the subject, including interviews, questionnaires
- [ ] Obtained from a foreign country or countries only
- [ ] Obtained from records open to the public
- [ ] Obtained from existing research records
- [ ] None of the above

If **derived from a medical record**, identify source:

VA CPRS

19.4 Identifiers may be included in research records:

○ Yes ○ No

If **yes**, check all the identifiers that may be included:

- [x] Names
- [x] Dates
- [x] Postal addresses
- [x] Phone numbers
- [ ] Fax numbers
- [x] Email addresses
- [x] Social Security Numbers*
- [x] Medical record numbers
- [ ] Health plan numbers
- [ ] Account numbers
- [ ] License or certificate numbers
- [ ] Vehicle ID numbers
- [ ] Device identifiers or serial numbers
- [ ] Web URLs
- [ ] IP address numbers
- [ ] Biometric identifiers
- [ ] Facial photos or other identifiable images
- [ ] Any other unique identifier

* Required for studies conducted at the VAMC

19.5 Identifiable information might be disclosed as part of study activities:

◉ Yes ○ No

If **yes**, indicate to whom identifiable information may be disclosed:

- [ ] The subject's medical record
- [ ] The study sponsor
- [ ] Collaborators
- [ ] The US Food & Drug Administration (FDA)
- [x] Others (specify below)
- [ ] A Foreign Country or Countries (specify below)

If **Others**, specify:

VA regulatory personnel

19.6 Indicate how data are kept secure and protected from improper use and disclosure (check all that apply): NOTE: Whenever possible, do not store subject identifiers on laptops, PDAs, or other portable devices. If you collect subject identifiers on portable devices, you MUST encrypt the devices.

- [ ] Data are stored securely in My Research
- [ ] Data are coded; data key is destroyed at end of study
- [x] Data are coded; data key is kept separately and securely
- [x] Data are kept in a locked file cabinet
- [x] Data are kept in a locked office or suite
- [x] Electronic data are protected with a password
- [x] Data are stored on a secure network
- [ ] Data are collected/stored using REDCap or REDCap Survey
- [ ] Data are securely stored in OnCore

19.7 Additional measures to assure confidentiality and protect identifiers from improper use and disclosure, if any:

Data will be kept on an encrypted network drive.

19.8 This study may collect information that State or Federal law requires to be reported to other officials or ethically requires action:

- ○ Yes
- ◉ No

Explain:

19.9 This study will be issued a Certificate of Confidentiality:

- ○ Yes
- ◉ No

20.0 Subjects

20.1 Check all types of subjects that may be enrolled:

- [x] Inpatients
- [x] Outpatients
- [ ] Healthy volunteers
- [ ] Staff of UCSF or affiliated institutions

20.2 Additional vulnerable populations:

- ☐ Children
- ☐ Subjects unable to consent for themselves
- ☐ Subjects unable to consent for themselves (emergency setting)
- ☐ Subjects with diminished capacity to consent
- ☐ Subjects unable to read, speak or understand English
- ☐ Pregnant women
- ☐ Fetuses
- ☐ Neonates
- ☐ Prisoners
- ☐ Economically or educationally disadvantaged persons
- ☐ Investigators' staff
- ☐ Students

Explain why it is appropriate to include the types of subjects checked above in this particular study:

Describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects and minimize coercion or undue influence:

21.0 Recruitment

21.1 * Methods (check all that apply):

- ☑ Study investigators (and/or affiliated nurses or staff) recruit their own patients directly in person or by phone.
- ☐ Study investigators recruit their own patients by letter. Attach the letter for review.
- ☐ Study investigators send a "Dear Doctor" letter to colleagues asking for referrals of eligible patients. If interested, the patient will contact the PI or the PI may directly recruit the patients (with documented permission from the patient). Investigators may give the referring physicians a study information sheet for the patients.
- ☐ Study investigators provide their colleagues with a "Dear Patient" letter describing the study. This letter can be signed by the treating physicians and would inform the patients how to contact the study investigators. The study investigators may not have access to patient names and addresses for mailing
- ☐ Advertisements, notices, and/or media used to recruit subjects. Interested subjects initiate contact with study investigators. Attach ads, notices, or media text for review. In section below, please explain where ads will be posted.
- ☐ Study investigators identify prospective subjects through chart review. (Study investigators request a Waiver of Authorization for recruitment purposes.)
- ☐ Large-scale epidemiological studies and/or population-based studies: Prospective subjects are identified through a registry or medical records and contacted by someone other than their personal physician. (Study investigators request a Waiver of Authorization for recruitment purposes.)
- ☐ Direct contact of potential subjects who have previously given consent to be contacted for participation in research. Clinic or program develops a CHR-approved recruitment protocol that asks patients if they agree to be contacted for research (a recruitment database) or consent for future contact was documented using the consent form for another CHR-approved study.
- ☐ Study investigators list the study on the School of Medicine list of UCSF Clinical Trials website or a similarly managed site. Interested subjects initiate contact with investigators.
- ☐ Study investigators recruit potential subjects who are unknown to them through methods such as snowball sampling, direct approach, use of social networks, and random digit dialing.
- ☐ Other

If **Other**, explain:

21.2 * How, when, and by whom eligibility will be determined:

The clinical nurses responsible for providing cardiac rehabilitation will determine eligibility by applying the study inclusion and exclusion criteria at the time patients are referred to cardiac rehabilitation.

21.3 * How, when, where and by whom potential subjects will be approached:

Eligible patients will be offered standard of care cardiac rehabilitation regardless of whether they wish to participate in the study. Most patients will be approached in the hospital (at the bedside). The research staff member will explain the benefits of cardiac rehabilitation and offer the patient the opportunity to participate in the study. If the patient agrees to participate in the study, a research staff member will obtain informed consent. If the patient declines to participate in the study, usual care will continue. If for some logistical reason consent cannot be obtained during a patient's hospitalization, and the patient still wishes to participate in the study, a member of the research staff will obtain informed consent prior to enrollment in the study. No study procedures will be conducted prior to obtaining consent.

21.4 * Protected health information (PHI) will be accessed prior to obtaining consent:

(•) Yes ( ) No

22.0 Waiver of Consent/Authorization for Recruitment Purposes

This section is required when study investigators (and/or affiliated nurses or staff) recruit their own patients directly.

22.1 * Study personnel need to access protected health information (PHI) during the recruitment process and it is not practicable to obtain informed consent until potential subjects have been identified:

(•) Yes

If **no**, a waiver of consent/authorization is NOT needed.

22.2 * A waiver for screening of health records to identify potential subjects poses no more than minimal risk to privacy for participants:

(•) Yes

If **no**, a waiver of authorization can NOT be granted.

22.3 * Screening health records prior to obtaining consent will not adversely affect subjects' rights and welfare:

(•) Yes

If **no**, a waiver of authorization can NOT be granted.

22.4 * Check all the identifiers that will be collected prior to obtaining informed consent:

- [x] Names
- [x] Dates
- [x] Postal addresses
- [x] Phone numbers

- [ ] Fax numbers
- [ ] Email addresses
- [x] Social Security Numbers*
- [x] Medical record numbers
- [ ] Health plan numbers
- [ ] Account numbers
- [ ] License or certificate numbers
- [ ] Vehicle ID numbers
- [ ] Device identifiers or serial numbers
- [ ] Web URLs
- [ ] IP address numbers
- [ ] Biometric identifiers
- [ ] Facial photos or other identifiable images
- [ ] Any other unique identifier
- [ ] None

Note: HIPAA rules require that you collect the minimum necessary.

22.5 * Describe any health information that will be collected prior to obtaining informed consent:

Health information related to inclusion and exclusion criteria will be collected from the patient's electronic medical record.

Note: HIPAA requires that you collect the minimum necessary.

22.6 * Describe your plan to destroy the identifiers at the earliest opportunity consistent with the research or provide a health or research justification for retaining the identifiers, or indicate and explain that retention is required by law:

All screening PHI will be maintained electronically on VA servers and will be kept indefinitely (and securely) until a VA policy on destruction of data is in place.

23.0 Informed Consent

23.1 * Methods (check all that apply):

- [x] Signed consent will be obtained from subjects and/or parents (if subjects are minors)
- [ ] Verbal consent will be obtained from subjects using an information sheet or script
- [ ] Electronic consent will be obtained from subjects via the web or email
- [ ] Implied consent will be obtained via mail, the web or email
- [ ] Signed consent will be obtained from surrogates
- [ ] Emergency waiver of consent is being requested for subjects unable to provide consent
- [ ] Informed consent will not be obtained

23.2 * Process for obtaining informed consent:

Informed consent will be obtained during a study interview at the San Francisco VA Medical Center and before any study interventions have been initiated. All subjects will have the opportunity to read the informed consent and have their questions answered. Participants will be able to decline to participate without affecting any of their care or their ability to access cardiac rehabilitation. One copy of the consent will be provided to the participant. One copy will be scanned into the EHR per VA regulations. One copy will be retained by study staff.

23.3 * How investigators will make sure subjects understand the information provided to them:

Participants will verbalize understanding of the study and be able to describe what will happen during the study.

24.0 Financial Considerations

24.1 Subjects payment or compensation method (check all that apply):

Payments will be (check all that apply):

- [ ] Subjects will not be paid
- [ ] Cash
- [ ] Check
- [x] Debit card
- [ ] Gift card
- [ ] Reimbursement for parking and other expenses
- [ ] Other:

Specify **Other**:

24.2 Describe the schedule and amounts of payments, including the total subjects can receive for completing the study. If deviating from recommendations in Subject Payment Guidelines, include specific justification below.

- $50 reimbursement for baseline assesment. Paid upon completion of assesment.
- $50 reimbursement for 3-month assessment. Paid upon completion of assessment.
- $50 reimbursement for 6-month assessment. Paid upon completion of assessment.
- The total amount any subject can receive for completing the study is $150

24.3 Costs to Subjects: Will subjects or their insurance be charged for any study procedures?

○ Yes ◉ No

If **yes,** describe those costs below, and compare subjects' costs to the costs associated with alternative care off-study. Finally, explain why it is appropriate to charge those costs to the subjects.

25.0 CTSI Screening Questions

25.1 * This study will be carried out at one of the UCSF Clinical Research Services (CRS) centers or will utilize CRS services. CRS centers are at the following sites:

- **SFGH Clinical Research Center**
- **Moffitt Adult Clinical Research Center**
- **Moffitt Hospital Pediatrics & NCRC**
- **Mount Zion Hospital Clinical Research Center**
- **Tenderloin Center**
- **CHORI Children's Hospital Pediatrics & Adult Clinical Research Center**
- **Kaiser Oakland Research Unit**
- **SF VA Medical Center Clinical Research Unit**

Please note: Effective 3/1/14, the CRS form will no longer be completed and submitted in iRIS. The CRS budget request form can be found at: https://accelerate.ucsf.edu/files/crs /BudgetRequest2015.docx. Follow the instructions on the form to submit. Even if you click 'Yes' to

this question, the form will no longer proceed to the Clinical Research Services (CRS) Application Form section.

○ Yes ◉ No

25.2 This project involves community-based research:

○ Yes ◉ No

25.3 This project involves practice-based research:

○ Yes ◉ No

26.0 End of Study Application

26.1 **End of Study Application Form** **To continue working on the Study Application: Click on the section you need to edit in the left-hand menu. Remember to save through the entire Study Application after making changes. If you are done working on the Study Application: Click Save and Continue. If this is a new study, you will automatically enter the Initial Review Submission Packet form, where you can attach consent forms or other study documents. Review the Initial Review Submission Checklist for a list of required attachments. Answer all questions and attach all required documents to speed up your approval.**