Human Studies Subcommittee (IRB II)
Department of Veterans Affairs Medical Center
Research and Development Service
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IRB APPROVAL - Amendment

Date: May 30, 2019
From: Terri M. Laufer, M.D., Chairperson
Investigator: Manik Chhabra, MD
Protocol: Connected Health to Decrease Opioid Use in Patients with Chronic Pain
ID: 01758 Prom#: 0001 Protocol#: N/A

The following items were reviewed and approved through Expedited Review:

- Amendment - Added exit survey to the study (05/07/2019)

Expedited Approval [Expedited under Federal Regulation: 45 CFR 46.110(b)(2) / VA Regulation: 38 CFR 16.110(b)(2)] was granted on 05/30/2019. This Expedited review will be reported to the fully convened Human Studies Subcommittee (IRB II) on 06/19/2019.

The following other committee reviews are scheduled:
Research & Development Committee [07/02/2019]

CMCVAMC SPECIFIC PROTOCOL SUMMARY
Corporal Michael J. Crescenz Department of Veterans Affairs Medical Center (CMCVAMC)
Institutional Review Board (IRB)

Section 1. General Information

Protocol Title: Connected Health to Decrease Opioid Use in Patients with Chronic Pain

CMCVAMC Protocol Version Number and Date: Version 5, 5/30/2019

Principal Investigator (PI) Name: Manik Chhabra, MD

PI's Academic Degree(s): *MD*

Is the study funded? *YES* **If "yes", specify funding agency:** *U Penn Institute for Translational Medicine and Therapeutics*

Is a grant application requesting funds for the study currently being reviewed? *NO*

CMCVAMC is the only institution involved: *YES*

CMCVAMC is the coordinating center in which the PI is the lead investigator: *NO*
If this answer is yes, complete the next two sections:

- **List the name(s) of the other site(s) involved.**
- **Provide the Federal Wide Assurance (FWA) numbers for each site.**

State name of coordinating center if this is not CMCVAMC.

Describe PI's qualifications to conduct this project, and attach a copy of PI's VA or NIH biosketch. Be specific in regard to PI's research experience. Manik Chhabra, MD is the Principal Investigator (PI) and a staff physician at the CMCVAMC in Philadelphia. He will be entering into the role of Medical Director of the Pain PACT whereupon this study will take place. He previously was a VA Advanced Research Fellow, and a fellow in the Robert Wood Johnson Clinical Scholars Program. He has experience in health services research, clinical trial design and analysis, and statistical analysis. He currently spends 50% of his effort on research and evaluation, and 50% on clinical and teaching activities.

Does any research staff member have an actual and/or perceived conflict of interest with this study? *NO* If yes, explain.

Is this study a clinical trial? *YES* **If yes, specify the type.** *Phase II*

State the estimated length of time to complete enrollment of subjects. *6-9 months*

State the expected duration of participation by individual subjects (including any follow-up, e.g., need to re-contact subject for follow-up questions prior to closure of the study). *12 weeks*

Specify the projected date of completion of the study. *05/31/2019*

Section 2: Participating Site Specifications

2.1. **Where will the research project be conducted? (Check all that apply)**

- ☐ **VA Inpatient Setting**
- ☐ **VA Laboratories**
- ☐ **University of Pennsylvania**
- ☐ **Other *(Specify)*:** ☐
- **X VA Outpatient Clinic/Office**
- **Subject Homes**
- ☐ **Community Based Outpatient Clinics (CBOCs)**

2.2. **If research is conducted at a non-VA site, please specify where and how much of the project will be conducted at that location.**

Section 3: Introduction

Provide scientific background and rationale for study. Including summary of gaps in current knowledge, relevant data, and how the study will add to existing knowledge. Chronic pain is a highly prevalent and costly condition in the US. An estimated 88.5 million adults suffer from daily pain, resulting in estimated cost of $500-635 billion due to lost productivity, and $261-300 billion in health care expenditures. To manage their chronic pain, 5 to 8 million Americans take an opioid medication daily. Yet, the risks associated with ongoing opioid prescription, including overdose, abuse and diversion, temper their analgesic effects. Opioids are not more effective in the treatment of chronic pain compared with non-opioid approaches. Current guidelines have adapted to the evidence, recommending opioid-sparing approaches for treating patients with chronic pain, and tapering for those on higher doses to safer levels of use. Tapering opioids, however, requires replacing them with effective non-opioid strategies. Improving mobility has been shown to improve pain and decrease medication use among patients chronically prescribed opiates. Concurrently, financial incentives and the use of behavioral incentives have been shown to promote mobility.

Appreciating the gains in health outcomes that can be made with "connected health" approaches, we propose a novel pilot study designed to evaluate if technology enabled care (TEC) strategies and financial incentives can improve patient mobility in our chronic pain population, reduce pain and decrease opioid use. Our primary aim is to determine if chronic pain patients who receive TEC-enhanced treatment with financial incentives demonstrate increased participation in activities that promote mobility (physical therapy, yoga, tai chi) in comparison to patients receiving usual care. Secondary outcomes will include whether increased activity participation also reduces pain severity and opioid use, and improves function and increases the number of daily steps taken. The results of this pilot will enable us to determine what strategies are effective at increasing mobility and if these gains translate into reduced pain and decreased opioid use. The Way to Health application, a research information technology platform at the University of Pennsylvania, will be used to track medication use.

Section 4: Objectives Section

4.1. **Describe the study's purpose, specific aims, or objectives.**

The objective of this pilot study to evaluate if behavioral incentives applied at the VA Medical Center can appreciably increase participation in activities that promote mobility, and subsequently reduce pain severity and opioid use.

Primary outcome: Activity participation (as measured by the Stanford Exercise Questionnaire) and increased mobility (as measured by wearable tracker).

Secondary outcomes: Opioid use (as measured by medication adherence and pill counts), physical function (as measured by PROMIS pain interference tool) and pain severity (as measured by PROMIS pain severity tool).

4.2. **State the hypotheses to be tested.**

Hypothesis: Behavioral financial incentives will lead to increased physical activity (as measured by the Stanford Exercise Questionnaire) and mobility (as measured by wearable tracker).

Section 5: Study Procedures

5.1. Study Design

5.1.1. Describe in detail the experimental design, i.e. from recruitment procedures to study closure.

Design. Forty patients will be enrolled in the proposed work. Participants will be randomly assigned to one of two groups for the 12-week intervention period: (1) usual care; or (2) TEC strategies with enrollment in a weekly regret lottery.

Sample and Setting. The sample will be comprised of patients receiving care at the Corporal Michael Cresenz VA Medical Center (CMCVAMC) in Philadelphia as well as at the Pain-focused Patient Aligned Care Team (P-PACT). This primary care clinic was instituted to provide comprehensive, evidence-based care to patients with chronic non-malignant pain and on opioid therapy. Patients referred to the program are those identified as high-risk related to being on high dose opioid therapy; on combined opioid/benzodiazepine therapy; and/or having a history of substance abuse. A key component of the P-PACT program is improving mobility amongst patients using modalities available through the VA, including physical therapy, yoga and tai chi, which have an evidence base to improve pain, sleep, cognitive and physical function as well as decrease medication use.

Inclusion Criteria	Exclusion Criteria
• Chronic non-malignant pain • High dose opioid therapy • Possession of activated cell phone with text messaging capabilities • Willingness to comply with study requirements	• Pain of malignant origin • Sensory impairments precluding use of text messaging and activity tracker • Physical disability precluding improvements in physical activity

Procedures. Eligible patients will be offered participation in this pilot study. The enrollment goal of 40 patients was chosen based on feasibility given the time-frame. Following informed consent, participants will be randomly assigned to one of the two study arms. All participants will be provided individual activity regimens, and be offered physical therapy, yoga, or tai-chi classes at the CMCVAMC. The activity goal will be participation in their activity regimen or classes at least twice per week, a frequency used in other studies promoting activity for chronic pain. Participants will self-report their activity, pain severity, functionality, and opioid use monthly via questionnaire and pill counts. Additionally, all participants will be provided an activity tracker to measure steps taken and instructed on use and data upload procedures. Upon the completion of their 12-week participation, participants are asked to complete an in-person exit survey answering questions about their experience in the study, the use of the FitBit activity watches, as well as the use of the FitBit application.

Those receiving the TEC-linked intervention will be familiarized with the text messaging process and the measures that will be administered via this technology. TEC will consist of a daily personalized text message from a dedicated research assistant reminding the patient to engage in their prescribed physical activity for the day. A second text message at the end of the day will direct the patient to return activity participation, pain severity, functionality, and opioid use data, and upload activity tracker data to the Way to Health (WTH) platform. The behavioral incentive provides the opportunity for subjects who meet their weekly activity goals to enter a lottery to receive either a small ($30) or large ($100) financial incentive. The lottery is structured such that subjects have an 18% chance/week of winning the small prize, and a 1% chance of winning the large prize. For those not meeting goals, they will be informed what they would have won had they met their goal. This design has been used in similar studies, with evidence showing the desire to avoid regret can be motivating.

Measures. The validated NIH PROMIS measures will be utilized to measure key study outcomes. Opioid use will be collected via the WTH Medication Adherence measure and monthly pill counts, and physical activity collected by self-report and a wearable activity tracker. In addition to collection of baseline demographic data and study experience data, study measures will be administered at the specified time points to evaluate the efficacy of the TEC intervention:

Measure	Tool	TEC administration

Pain severity	PROMIS Pain Intensity	Daily via text
Function	PROMIS Pain Interference	Daily via text
Opioid use	Medication Adherence tool,	Daily
	Pill counts	Beginning and End
Physical activity	Stanford exercise questionnaire	Weekly via text
	Wearable activity tracker	Weekly download
Anxiety, depression, general well-being	PROMIS-29 profile	Monthly
	PHQ9	Monthly

Investigative team: Our interdisciplinary team includes a wealth of experience, including nationally known researchers in chronic pain (Compton), as well as the medical director of the new Pain-PACT (Chhabra). In addition, our team boasts expertise in connected health interventions using behavioral incentives (Chaiyachati).

Study Timeline. Study start-up procedures, including IRB approval and development of text messaging intervention, will take place during the first 3 months of the funding period. Subject recruitment will begin in month 4 and end in month 7, with data collection completed by study month 10. Months 11 and 12 will be devoted to data analysis and dissemination activities.

5.1.2. **What research methods will be used in the project? *Check all that apply.***

X Surveys/Questionnaires ☐ **Interviews** ☐ **Audio Taping**

☐ **Behavioral Observations** ☐ **Chart Reviews** ☐ **Video Taping**

☐ **Focus Groups** **X Randomization** ☐ **Double-Blind**

X Control Group ☐ **Placebo** ☐ **Withhold/Delay Treatment**

☐ **Specimen Collection**

☐ **Deception** **Telephone Survey**

X Other (Describe) Mobility tracking via a wearable device.

5.1.3. **Provide description of the study population (delineate all categories of subjects – male, female, inpatients, outpatients, providers, family members, employees, etc.). Include anticipated initial enrollment numbers (and number of subjects anticipated to complete all aspects of the protocol).**

The study population will include 40 participants total: 1) adults age 18 years or older; 2)Chronic non-malignant pain; 3) High dose opioid therapy; 4) Possession of activated cell phone with text messaging capabilities; and 5) willingness to comply with study requirements.

5.1.4. **As applicable, provide rationale and information on any added protections and safeguards for vulnerable populations (children, prisoners, pregnant women, physically or mentally-disabled persons, and economically or educationally disadvantaged persons).**

This will not include children or prisoners. For other vulnerable populations, this study will only include subjects wishing to participate. Those individuals with sensory impairments precluding use of text messaging and activity tracker, or with physical disability precluding improvements in physical activity will not be included in the study.

5.1.5. Does this project target a specific race or ethnic group as subjects? ***NOT APPLICABLE***

If yes, check all that apply.

Race **Ethnicity**

☐ **American Indian or Alaska Native**

☐ **Asian**

☐ **Black or African American**

☐ **Native Hawaiian or other Pacific Islander**

☐ **White**

☐ **Other**

☐ **Hispanic or Latino**

☐ **Not Hispanic or Latino**

5.1.6. Will this study bank/store specimens for future research? *NO*

5.1.6.1. **If yes, include information on specimens to be banked/stored.**

5.1.6.2. **If specimens will be banked/stored, specify location.**

5.1.6.3. **If the location of the specimen bank is a non-VA site, has the mandatory approval from VA Central Office been obtained through submission of a tissue banking application?** *Choose an item.*

5.1.6.3.1. **If yes, provide a copy of the response from VA Central Office.**

5.1.6.3.2. ***IF BANKING SPECIMENS, IT MUST BE AT A VA APPROVED FACILITY. (For additional information, go to the following website http://www.research.va.gov/programs/tissue_banking/, or contact the IRB office.)***

5.1.6.4. **If applicable, explain how destruction of banked samples will be substantiated.**

5.1.6.5. **Do you anticipate using the banked specimens for other studies beyond the defined study period and defined study parameters?** *Choose an item.*

5.1.6.5.1. **If yes, will you need to re-contact subjects? How will this be done?**

5.1.7. **Will this study create a data repository for future studies?** *NO*

5.1.7.1. **If yes, describe and/or provide the following:**

5.1.7.1.1. **The type of data (identified or de-identified) including what protected health elements are to be collected.**

5.1.7.1.2. **The source from which data will be collected (e.g., subjects, non-research data repositories, research data repositories, publicly available, VA source, non-VA source.**

5.1.7.1.3. **How and where the data will be stored (e.g., electronic, paper records, approved VA-owned or VA-leased space).**

5.1.7.1.4. **How the data will be transmitted, if applicable.**

5.1.7.1.5. **How the data will be secured during storage, use, and transmission both during the conduct of the research protocol and after the protocol is completed.**

5.1.7.1.6. **Plans to store data for future research. If the data is stored for future research, there must be a description of a research data repository, its location, and its security measures.**

☐

5.1.7.1.7. **Plans to share with others including other researchers (VA and non-VA). If the data were collected through a research project, discussion of whether or not the original informed consent allowed for such reuse of the data and if the reuse is consistent with the HIPAA authorization that was obtained.**

☐

5.1.7.1.8. **Justification for the use of any identifiers.**

☐

5.1.7.1.9. **Justification that the data requested represent the minimum necessary to conduct the research.**

☐

5.1.7.1.10. **A discussion of plans for obtaining informed consent and HIPAA Authorization, or for requesting the IRB to waive these requirements. If the investigator requests that the requirement for a HIPAA Authorization be waived, justification for this request must be included in information submitted to the IRB.**

☐

5.1.7.1.11. **In addition to the above, provide a Standard Operating Procedures Manual for the data repository.** *Contact IRB office for additional details.*

5.2. **Subject Recruitment Methods**

5.2.1. **State how many subjects will be needed**: 40 total subjects, with 20 in each arm of the study.

5.2.2. **Who will be responsible for recruiting potential subjects? Provide titles of individuals.**

The study team will include:

Manik Chhabra, MD – Principal Investigator
Peggy Compton- Co-Principal Investigator
Tanisha Dicks, MBA– Project Manager

5.2.3. **How will initial contact with potential subjects be made? (*e.g., local clinics, physician referrals, letters to prospective subjects)***

Veterans will be informed of the opportunity to participate in the study by Dr. Chhabra and provided with a copy of a study flyer, and study contact information. The study team will call the veteran 7 days provision of materials. If an individual is interested in the study, they will be asked to review the informed consent and be given the opportunity to ask questions. Once a signed informed consent is returned to the study team, a visit with the veteran will be scheduled to conducted eligibility and baseline surveys. The study team will provide the veteran a wearable device to track step counts and provide instructions to create an account by which they will transmit de-identified step data to the research team and how to access and use the WTH application.

5.2.4. **Will you be using any of the following methods to recruit subjects? (Check all that apply.)**

☐ **Local database for which subjects have NOT given prior permission to be contacted for Research.**

XX☐ **Personal contact with patients over whom you have direct/indirect oversight**

☐ **Provider (Clinician) Referrals of potential subjects**

5.2.5. **Indicate the types of recruitment/advertisement materials that will be used: Check all that apply. Submit copies of recruitment materials, for IRB review.**
***X* Not applicable; none to be used**
☐**Fliers** ☐**Newspapers** ☐**Letters** ☐**Websites** ☐**Television**
☐**Radio** ☐**Audio** ☐**Video** ☐**Surveys**
☐**Other (Specify, e.g. employee newsletters)** ☐

5.2.6. **Non-Veteran Subjects will be given a copy of the Notice of Privacy Practices.** *NOT APPLICABLE*

5.3. **Compensation for Participation** - *YES* **If yes, complete the following.**
5.3.1. **Summarize any financial compensation that will be offered to subjects.**
All participants will receive $75 to for completing the entire 12-week study. As noted above, they also have the possibility of receiving a financial incentive via a lottery process for meeting activity goals.

5.3.2. **Provide the schedule for compensation.**
5.3.2.1. **Per study visit or session.**
N/A
5.3.2.2. **Total amount for entire participation.**
$75 if subject completes the entire 12-week study.
5.3.3. **State how compensation will be provided:** *Voucher*

5.4. **Informed Consent Procedures**
5.4.1. **Indicate if informed consent will be obtained and/or if you are requesting a waiver of informed consent or waiver of documentation of informed consent.** *Consent to be obtained*

5.4.2. **If the research involves multiple phases, specify for which phases of the research the waiver(s) is/are being requested.**
N/A

5.4.3. **Describe circumstances, if any, that may need to be addressed in seeking informed consent (e.g., subjects with impaired decision making ability and the use of a legally authorized representative, etc.)**
Not applicable.

5.4.4. **If applicable, indicate how study personnel will be trained regarding human subjects protections requirements and how to obtain and document informed consent.**
All study personnel will have completed the required human subjects, HIPAA, and information security and privacy trainings at the VA.

5.4.5. **Inclusion/Exclusion Criteria: Describe the criteria that determine who will be included in or excluded from the study.**
5.4.5.1. **Inclusion Criteria**

1) adults age 18 years or older; 2) Chronic non-malignant pain; 3) High opioid therapy; 4) Possession of activated cell phone with text messaging capabilities; and 5) willingness to comply with study requirements.

5.4.5.2. **Exclusion Criteria**

1) Pain of malignant origin; 2) Sensory impairments precluding use of text messaging and activity tracker; or 3) Physical disability precluding improvements in physical activity.

5.5. Withdrawal of Subjects

5.5.1. **Describe how a subject can withdraw from the study.**

Subjects may withdraw at any point by informing the study team in person, by written mail or by phone.

5.5.2. **Describe any anticipated circumstances under which subjects will be withdrawn from the research without their consent.**

None.

5.5.3. **Describe the consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject (e.g., the subject contacting the investigator for an end-of-study visit).**

Patients choosing to withdraw early in the study will not receive the total compensation as described above, but will receive pro-rated payment of $6/wk for each week completed. Patients are free to, at any time, contact the study team to be removed from the study. Withdrawn patients will be asked to complete an exit survey with the option of completing in-person or over the phone answering questions about their experience in the study, the use of the FitBit activity watches, as well as the use of the FitBit application.

5.6. Potential Risk/Benefit Analysis

5.6.1. Potential Study Risks

5.6.1.1. **Describe and assess all of the following risks that may be associated with the research:**

5.6.1.2. **Physical**

To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a physical activity study. The program will use a gradual increase in physical activity during the first month that should pose little health risk to participants. Participants are given guidance on when to seek medical attention and a reporting protocol is in place to capture any changes in symptoms with physical activity.

5.6.1.3. **Psychological:** Not applicable.

5.6.1.4. **Social/Economic:** Not applicable

5.6.1.5. **Legal:** Not applicable.

5.6.1.6. **Loss of Confidentiality**

A potential risk of this study is a breach of participant confidentiality. We will minimize this risk by using secure data methods as described previously. Names and addresses will be stored in encrypted databases. These data will be viewable only by the respective participants and the study coordinator. All other members of the research team will be able to view only participant ID numbers. There will be no functionality in the web application to export a dataset with identifiable information. Even the study arms will be identified by code letters until both the statistician and PI agree that analysis is complete.

5.6.1.7. **Other, e.g. radiation, placebo, washout of medications:** Not applicable
5.6.1.8. **Assess the likelihood and seriousness of such risks.**: Not applicable

5.6.2. **Include a description of how anticipated risk will be minimized and include an analysis of risk vs. potential benefit.**
Anticipated risks of this study should be minimal and the risk/benefit ratio is very favorable. To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in this study. We have previously outlined the procedures that will be used to prevent a breach of participant data.

5.6.3. **Potential Study Benefits**
5.6.3.1. **Indicate potential benefits to be gained by the individual subjects, as well as benefit(s) that may accrue to society in general as a result of the planned work. If the subject will not receive any direct benefit, this fact must be stated here and in the consent form.**
Through participation in this study, each participant will have the potential to increase physical activity which could improve their health and reduce their opioid use. If this approach is effective, it could have tremendous benefits for society if adopted on a wide scale to help individuals. It is expected that other people will gain knowledge from this study and that participation could help understand how to effectively motivate individuals to change behavior. Participants may also receive no benefit from their participation in the study.

5.6.4. **Alternative Treatments Outside the Study**
5.6.4.1. **Describe alternatives available to the subject outside the research context. If there are no such alternatives, state that the alternative is not to participate in the research study.**
The alternative is not to participate in the research study.

5.7. **Data Monitoring**
5.7.1. **Will a Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) oversee the project?** NO
5.7.1.1. **If yes, provide contact information for the DSMB or DMC representative.**
5.7.1.2. **If no, describe the data and safety monitoring plan to be followed.**
The Principal Investigator will be responsible for monitoring the study. All participants will be given anticipatory guidance on when to seek medical attention. In addition, participants will be asked to report to the study team any injuries or medical care that they feel resulted from participation in the study. They can either present in person, call the study team or send an email. The research coordinator will call the participant to collect information regarding the issue and then the PI will review and determine whether it is ok to proceed, further investigation is needed, or the participant should stop the study. For this study, there will be no stopping rules or endpoints and thus no planned interim analyses.

5.8. **Reporting of Protocol Deviations, Adverse Events (AEs), Serious Adverse Events (SAEs), Breaches of Confidentiality, Unanticipated Adverse Device Effects (UADEs), and Unanticipated/Unexpected Problems**
5.8.1. **Include procedures for reporting these events to the CMCVAMC IRB and sponsor.**
Standard protocol will be followed for any events including reporting to the CMCVAMC IRB within 5 business days of discovery. We will use the CMCVAMC serious-adverse event form for reporting SAEs, UADEs, and any other unanticipated/unexpected problems. We will also use the CMCVAMC Protocol

Deviation form for reporting any protocol deviations. Any true adverse events will be reported immediately.

5.9. **Privacy and Confidentiality**

5.9.1. **Describe whether the study will use or disclose subjects' Protected Health Information (PHI).**
In order to provide subjects with compensation for enrollment, the study will collect PHI. No PHI will be disclosed to any person outside of the research team.

5.9.2. **Check the PHI to be collected on all subjects for this research protocol.**

- X **Name**
- X **All geographic subdivisions smaller than a State, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census:**
  a. **The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people; and**
  b. **The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.**
- X **All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.**

X **Telephone numbers** ☐ **Fax numbers**
X **Electronic mail addresses** X **Social Security/Medical Record Number**
☐ **Health plan beneficiary numbers** ☐ **Account Numbers**
☐ **Certificate/license numbers**
☐ **Vehicle identifiers and serial numbers, including license plate numbers**
☐ **Device identifiers and serial numbers**
☐ **Web universal resource locators (URLS)**
☐ **Internet protocol (IP) address numbers**
☐ **Biometric identifiers, including fingerprints and voiceprints**
☐ **Full-face photographic images and any comparable images**
☐ **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.**
☐ **HIV (testing or infectious disease) records** ☐ **Sickle cell anemia**
☐ **Drug Abuse Information** ☐ **Alcoholism or Alcohol Use**

5.10. **Information Security**

5.10.1. **List the data/information that will be stored (including signed, original informed consent and HIPAA authorization forms, if applicable, case report forms, etc.)**
Stored data and information will include: patient information including name, last 4 of SSN, date of birth, BMI, medical, problem list, signed, original informed consent forms, medication usage, baseline questionnaires capturing participants' sociodemographic information, technology

assessment, and current level of physical activity, any responses from follow-up phone/in-person interviews/surveys.

5.10.2. **Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, Certificates of Confidentiality and separation of identifiers and data).**

All study personnel will complete the required human subjects, HIPAA, and information security and privacy trainings at the VA. Each Veteran who enrolls in this study will be assigned a unique, random patient ID number generated for the purposes of this study. To protect each participant's identity, the link between the Veteran's name, last 4 of SSN, date of birth, and patient ID number will be a password protected file stored on a secure VA server and accessible only to research staff. In all subsequently created analytical files, participants will only be identified by their patient ID number, without inclusion of his/her name, SSN, or date of birth. Subject questionnaires will be either directly inputted into a computer database or written onto paper forms and then transferred to a database at a later time. Interview transcripts will be produced electronically and will be housed on a secure VA server as well. No results will be reported in a personally identifiable manner.

5.10.3. **Indicate how and where data/information will be stored, and specify pertinent security systems.**

The file linking Veterans' personal identifying information, patient database, questionnaire data, and interview transcripts will be password protected and stored on a secure VA server located within the VA firewall. The server is physically located within the FITS computer room of the Philadelphia VAMC and networked within the VA Intranet. Thus, the servers have the same degree of physical and electronic protection afforded other VA computer systems, including antiviral protection and routine back-ups. FITS is responsible for managing the server hardware and software, including its physical and network security and connectivity, backup processes, operating system patches, and application management. Study data will be accessed using password protected computers that are not connected to the Internet and are entirely compliant with Federal Information Security Management Act (FISMA) standards. Paper records will be kept in a locked file cabinet in an electronically secured building. The likelihood of loss of confidentiality is very low given the information security and privacy requirements that are in place.

The study will use the "*Way to Health*" (WTH) platform to provide close monitoring, feedback and reinforcement at a low cost to permit cost-effective flexible, scalable infrastructure. This platform has been used for clinical trials at the CMCVAMC in the past. The platform was built at the University of Pennsylvania and aims to improve health behaviors and consists of a portal with links to variety of peripheral devices (e.g., scales, wearable devices, glucometers) for assessing health behaviors and outcomes; the capacity to communicate back to patients using interactive voice recording; and the ability to automate the delivery of feedback reports. For this study, medication use and step goal data will be collected via the platform.

Once patients have consented to be in the study and have their data managed by WTH, the WTH platform adherence tracking information will be stored according to a unique, random, patient identifier generated for the purposes of the study. To assure that subject, physician and other informant confidentiality is preserved, individual identifiers (such as name and medical record number) are stored in a single password protected system that is accessible only to study research, analysis and IT staff. This system is hosted onsite at the University of Pennsylvania (UPenn) and is protected by a secure identification number (ID). Any datasets and computer files that leave the firewall will be stripped of all identifiers and individuals will be referred to by their study ID. The study ID will also be used on all analytical files.

The University of Pennsylvania Biomedical Informatics Consortium (BMIC) is the hub for the hardware and database infrastructure. The data collected for WTH based studies is stored in MySQL databases on a BMIC-operated blade server environment devoted specifically to WTH. The data center is housed in the Information Systems and Computing at 3401 Walnut Street. All data are stored in a single relational database, allowing researchers to correct mistakes. Every SQL transaction, including accessing and changing data is logged for auditing purposes. Data are entered into the database through several different mechanisms. A program specialist will enter subjects' unique, random patient identifier and responses to survey questions through a PHP-based web interface (which is based at the BMIC, as noted above). Data from monitoring devices are uploaded automatically. Datasets are blinded of all personally identifiable information when exported for analysis. The web application automatically removes all identifiers when a member of the research team requests an analytic dataset. The only people with access to identifiable participant information are pre-specified Research Coordinators responsible for contacting participants. Personal information and research data will be stored in separate SQL tables and will be linked by a computer-generated ID number. All data for this project will be stored on the secure/firewalled servers for the BMIC Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by UPenn system managers. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health System medical records, greatly minimizes the risk of loss of privacy.

5.10.4. **Will PHI be transmitted or transported outside of CMCVAMC?** *NOT APPLICABLE*
As noted above, all PHI will be stored on a VA server located behind a VA firewall.

If yes, complete sections 5.10.4.1 through 5.10.4.3, and an Off-site Storage/Transfer of Research Data form. If no, go directly to section 5.11.

5.10.4.1. **Does the informed consent document and Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research form disclose entities/individuals to which/whom PHI will be transported or transmitted?** *Choose an item.*

5.10.4.2. **Specify entities/individuals outside CMCVAMC to which/whom data will he disclosed, the justification for such disclosure and the authority, and how they will access it.**

5.10.4.3. **List the data/information that will be transmitted or transported, and specify how data will be transported or transmitted from one location to another and how it will be protected during transmission or transportation outside of CMCVAMC.**

5.11. **Data Management Access Plan**

5.11.1. DMAP form **must** be included with all **initial** submissions. The DMAP form can be found on the Research and Development SharePoint site.

5.12. **Communication Plan**

5.12.1. **Include plan for ensuring that the study is conducted according to the IRB-approved protocol.**

All study personnel will meet regularly to ensure that the study is conducted according to the IRB approved protocol. At these meetings, they will discuss unforeseen challenges as they arise and together create a plan for troubleshooting these issues within the confines of the IRB approved protocol.

5.13. **Is this Study Investigating the Use of a Drug or Biological Agent?** NO **If yes, complete the rest of this section. If no, go directly to section 6, unless 5.13 applies.**

5.13.1. **Specify if the drug or biological agent is:**

5.13.1.1. **FDA approved:** *Choose an item.*

5.13.1.2. **Used for off-label purposes:** *Choose an item.*

5.13.2. **Include the FDA Investigational New Drug (IND) number for all non-FDA approved and off-label drugs, biological agents or nutritional supplements. If not applicable state, "Not Applicable."**

5.13.3. **Provide all relevant information about the drug, including pre-clinical data.**

5.13.4. **Explain any wash-out periods, rescue medications permitted and any type of medications not permitted while enrolled in the study.**

5.13.5. **Describe blinding and un-blinding procedures.**

5.13.6. **Include the dosage, route of administration, previous use, and the safety and efficacy information on any drug used for research purposes.**

5.13.7. **Describe rationale for the dosage in this study.**

5.13.8. **Justify why the risks are reasonable in relation to anticipated benefits and/or knowledge.**

5.13.9. **Describe where drug preparation will be done.**

5.13.10. **All drugs for CMCVAMC subjects must be dispensed through the VA investigational pharmacy.**

5.13.11. **Describe where the study treatment will be administered.**

5.13.12. **Describe plan for tracking a non-compliant treatment study subject.**

5.13.13. **Describe the process for the storage, security, dispensing and return of an investigational drug.**

5.13.14. **Has this protocol has been submitted to the Medical Center's Pharmacy and Therapeutics Committee?** *Choose an item.*

5.14. **Is this Study Investigating the Use of a Device** - *NOT APPLICABLE* **If yes, complete the rest of this section. If no, go directly to section 6.**

5.14.1. **The Investigational Device Exemption (IDE) number must be submitted for all significant risk devices and if an IDE exists for a non-significant risk device.**

5.14.2. **Significant Risk or Non-significant Risk - If a device is not approved by the FDA, specify whether or not the sponsor has determined this device to be a "significant risk" or "non-significant risk" as defined by the FDA.**

5.14.3. **Provide all relevant information about the device.**

5.14.4. **Describe blinding and un-blinding procedures.**

5.14.5. **Specify if device is:**

5.14.5.1. **FDA approved:** *Choose an item.*

5.14.5.2. **Used for off-label purposes:** *Choose an item.*

5.14.6. **Explain if the investigational device will be delivered and/or stored by the Principal Investigator or Pharmacy Service.**

5.14.7. **Describe the process for the storage, security, dispensing and return of an investigational device.**

5.14.8. **For research involving an investigational device, describe the SOP or plan for device control.**

5.14.9. **Address how the device will be stored in such a way that only research staff associated with the protocol will have access to the device.**

5.14.10. **Describe measures that will be put into place to ensure that the device will only be used in subjects of this research protocol.**

Section 6: Resources and Personnel

6.1. **Include where and by whom the research will be conducted.**

The study will be coordinated out of the CMCVAMC . The team includes: Manik Chhabra, MD (Principal Investigator), Peggy Compton (Co-Principal Investigator),Tanisha Dicks, MBA (Project Manager) and Elina Medvedeva (Statistician).

6.2. **Provide a brief description of each individual's role in the study. Indicate who will have access to protected health information and who will be involved in recruiting subjects; obtaining informed consent; administering survey/interview procedures; and performing data analysis.**
The team includes: Manik Chhabra, MD (Principal Investigator),-Peggy Compton (Co-Principal Investigator),Tanisha Dicks, MBA (Project Manager) and Elina Medvedeva (Statistician). These team members will only have access to PHI and will be working collectively to recruit subjects, obtain consents and administer surveys. Dr. Chhabra will perform data analysis.

6.3. **If applicable, provide information on any services that will be performed by contractors, including what is being contracted out and with whom.**
Not applicable.

6.4. **If applicable, provide information on any Memoranda of Understanding (MOUs) or Data Use Agreements (DUAs) that are being entered into, including with whom and for what reason.**
Not applicable.

Section 7: Genetic Testing

7.1. **Does the project involve genetic testing?** *Not Applicable, SKIP TO SECTION 8*

7.2. **Will specimens be kept for future, unspecified use?** *Choose an item.*

7.3. **Will samples be made anonymous to maintain confidentiality?** *Choose an item.* *(If there is a link, it is not anonymous. Coding is not anonymous.)*

7.4. **Will specimens be destroyed after the project-specific use is completed?** *Choose an item.*

7.5. **Will specimens be sold in the future?** *Choose an item.*

7.6. **Will subjects be paid for their specimens now or in the future?** *Choose an item.*

7.7. **Will subjects be informed of the results of the specimen testing?** *Choose an item.*

7.8. **Are there any implications for family members based on specimen testing results?** *Choose an item.*
7.8.1. **If answer to section 7.8 is yes, they may be subjects.**

7.9. **Will subjects be informed of results obtained from their DNA?** *Choose an item.*

7.10. **Explain if the study is looking for an association between a genetic marker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value.**

7.11. **Describe if the study is based on the premise that a link between a genetic marker and a specific disease or condition is such that the marker is clinically useful in predicting the development of that specific disease or condition.**

7.12. **Will the subject be notified of the results and the provision for genetic counseling?** *Choose an item.*

Section 8: International Research

8.1. **Does this study involve international research?** *NOT APPLICABLE* **If no, go directly to section 9.**

Section 9: Statistical Analysis

9.1. **Include statistical power calculations and the assumptions made in making these calculations.**
Being a pilot study, the enrollment goal of 40 patients was chosen based on feasibility given the time-frame as opposed to formal power analysis.

9.2. **Define plans for data and statistical analysis, including key elements of the statistical plan, stopping rules and endpoints.**
Data from the clinical trial will be analyzed using statistical software in SAS or R. Changes in pain severity, function, opioid analgesic use and physical activity over time will be compared between subjects assigned to each study arm. Regression analyses will be completed to assess if baseline patient characteristics impact the efficacy of the TEC-linked behavioral incentive intervention on key study outcomes.

9.3. **Provide sample size determination and analysis (include anticipated rate of screen failures, study discontinuations, lost to follow-up, etc.)**
See above.

9.4. **Describe how, where and by whom the data will be analyzed.**
The data will be analyzed by Dr. Chhabra and Peggy Compton with the help of a contracted statistician (Elina Medvedeva).

Section 10: References

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Connected Health Exit Survey

Approved by CMCVAMC IRB 2 on 5/30/2019

Thank you for participating in our study!

Now that you have completed your participation, we would like to know your thoughts about using the cell phone app by completing this short survey. Note that your responses will be anonymous and will improve future studies.

Please indicate the degree to which you agree with the following statements.

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. I found it easy to answer surveys on my cell phone.				
2. I found it easy to sync my steps to my Fitbit app.				
3. I found it easy to remember to wear and charge my Fitbit watch every day.				
4. I experienced technical difficulties in using the Fitbit app and/or filling out the surveys on my cell phone.				
5. I found the daily reminders helped me remember to complete study-related activities (i.e., complete study surveys, engage in physical activity).				
6. I felt that there were too many text messages each week.				
7. I felt that there were too many surveys to complete.				
8. I would be willing to participate in another study that uses the Fitbit app and cell phone-delivered surveys.				

9. What is your age?

10. Please select the type of phone you have:

iPhone Android Other (please name):

11. Please select: Male Female

12. Any other comments you wish to share (either on the technology or any other aspects of the study)? We are particularly interested in challenges you faced in using technology for this study.