Consent to participate as a Research Subject in:

MOTIVATE Walking

SUMMARY OF STUDY: *The purpose of this study is to identify the optimal conditions for encouraging Veterans to increase their physical activity. Participants will have the opportunity to earn financial or non-financial incentives for increasing their step counts. Participation in this study involves wearing a Fitbit device for 26 weeks, participating in 3 surveys, and potentially participating in a phone interview.*

We are inviting you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

Principal Investigator:

Research Staff:

Study Title:
Multiphase Optimization Trial of Incentives for Veterans to Encourage Walking

This study is being conducted by the VA Puget Sound Health Care System through a grant from the VA Health Services Research & Development Service.

1. Who can I contact with questions while I am in this study?

During business hours (8:00 a.m. – 4:30 p.m.), please call the Study Coordinator or Principal Investigator at ( ) - . After business hours (nights and weekends), please call ( ) - and ask the operator to page the on-call primary care physician.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at ( ) - if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

2. What is the purpose of this research study?

The purpose of this study is to examine how different study procedures and different types of incentives affect motivation for increasing physical activity (walking). This study is considered research because it will test different types of incentives compared to participants' daily and weekly step counts.

You may be eligible to participate if you are physically inactive, 50-70 years old, have a diagnosis of hypertension, depression, diabetes, are overweight and own an Android or iPhone smartphone that you're willing to use in this study.

We will be enrolling up to 200 subjects in the study. Your participation in the study will last approximately 6 months. The time required to participate in this study will be approximately 15-20 hours.

The study is considered research.

3. What will I be asked to do in this research study?

You will be asked to wear a Fitbit device every day for a period of 26 weeks, and to sync your Fitbit to the Fitbit app on your phone on a daily basis. The 26-week period includes a 2-week assessment period, a 12-week trial period, and a 12-week habit maintenance period.

We will provide you with a Fitbit Inspire 2, a wireless device that tracks the number of steps you take. This device is worn on your wrist. You may keep the Fitbit after the study is over. We will explain how to set up, sync, and use the Fitbit Inspire. We will walk you through how to download the Fitbit app to your smartphone. You must have either a Google Play or Apple ID account in order to download the app. Please be sure to have your Bluetooth and location services turned on so the app can sync to your Fitbit device.

Once the Fitbit app is downloaded to your smartphone, we will have you sign into a Fitbit account created for the study. In order to protect your identity, the account will be connected to false personal information. If you have a personal Fitbit account, you will be asked to use the study-created account instead. Please note that even though the demographic data connected to your study-created Fitbit account will not be connected to your identity, Fitbit may be able to obtain some personal information about you through phone permissions (e.g., location, phonebook, etc.). This is commonplace for many smartphone apps.

We encourage you to sync your Fitbit Inspire 2 on a daily basis. You will be paid $25 for enrolling in the study if you have been vendorized with VA Puget Sound Health Care System. Research study staff will assist you with this process.

You will also be asked to complete three surveys either online, over the phone or on paper, and you may be asked to participate in a phone interview about your experience participating in the study.

Pre-Trial: FITBIT SETUP AND BASELINE SURVEY. After you've enrolled in the study, we will mail you the Fitbit Inspire 2 device and instructions for setting it up. We will walk you through the setup process over the phone. The Fitbit setup visit will be your second visit with research staff. You will receive $25 for participating in this visit if you have been vendorized with VA Puget Sound Health Care System.

The baseline survey will be completed online, over the phone with a research coordinator or completed on paper and returned in a prepaid envelope. The survey will include questions such as, "Is there someone available to you who shows you love and affection?" and "In the past 2 weeks, how often have you been bothered by feeling bad about yourself, or that you are a failure, or have let yourself or your family down?" You may refuse to answer any questions that you do not wish to answer. The two follow-up surveys will also be completed online, over the phone or as a paper and returned to the research staff.

You will not be able to start participating in the study until the research staff have your baseline survey responses. For completing the baseline survey, you will receive $25. If you are eligible for participating in the full study, you will find out what group you have been randomized to after completing the survey and the two-week assessment period.

Pre-Trial: TWO WEEK ASSESSMENT PERIOD. We will collect preliminary data from you during the 14-day assessment period. During this time, we ask that you wear and sync your Fitbit daily, and walk as you normally would. During this week we will make sure that you are able to sync your Fitbit device.

At the end of 2-week assessment period, research study staff will call you to tell you if you are eligible to continue to participate. You may be ineligible for the study or you may be eligible to continue to participate.

If you are eligible to participate, research staff will explain when your week 1 will start, what group you have been randomized to and answer any other questions you may have.

If you are not eligible to participate in the full trial, you will still receive $25 for the enrollment visit, $25 for the Fitbit visit, and $25 for completing the baseline survey for a total of $75.

Pre-Trial: GROUP RANDOMIZATION. To randomize you to a study group, coordinators will draw from opaque envelopes containing the treatment assignment, which will be created by a computerized random number generator. You will find out what group you have been randomized to after completing the baseline survey. The two main randomizations that will occur relate to what incentives you can earn during the study and how you can earn incentives. There is a 50/50 chance of being randomized into each of the conditions in the table below. You may also be randomized to fill out pre-commitment postcards about your motivation to become more active and/or be randomized to provide physical activity or health advice to other Veterans. There is a 50/50 chance of being randomized to each of these conditions as well.

Randomization	*Options*	*Chance of either option*
Type of incentive	Financial or non-financial	50/50
Way to earn incentive	Lottery or loss-framed	50/50
Pre-commitment postcards?	Yes or no	50/50
Give advice to other Veterans?	Yes or no	50/50

Trial Weeks 1-12: INCENTIVES FOR WALKING. You will wear your Fitbit device every day and will sync it to your phone on a daily basis or as often as you can. There are a few smartphones where syncing should happen automatically if the Fitbit is close enough to your phone. You should periodically check to ensure your Fitbit and the Fitbit app are syncing. You will get daily texts or emails reminding you of the study activities for that given day. The text or email reminders may be to sync your device, notification of your new step goal, notification of if you have earned an incentive, updating you on your daily point/dollar value, reminding you to take/return a survey and giving you messages of encouragement. Your goal will be to increase your daily steps by approximately 15% each week. You will never be asked to walk more than 7,000 steps a day. You will receive a text and/or email message informing you of the new goal on your selected day of the week.

TYPE OF INCENTIVE: Financial or Non-financial. During the 12-week incentives period (Weeks 1-12), you will be randomized to have the opportunity to receive either money or points to redeem for items if you achieve your step goals. At the end of the 12-week incentives period, if you are in the financial incentives group, you will receive a direct deposit for the total amount that you earned. If you are in the non-financial incentives group, you will get to select item(s) that corresponds to your point total. These will then be mailed to you.

WAY TO EARN INCENTIVE: Lottery or loss-framed. You will be randomized to either a lottery or loss-framed method of earning incentives. If you're in the lottery group you'll have an approximately 18% chance of earning $7 (or 7 points) every day that you hit your target steps, and an approximately 1% chance of earning $75 (or 75 points).

If you're in the loss-framed group, you will begin every week with $14 (or 14 points) and will lose $2 (or 2 points) every day of the week that you do not hit your step goal.

PRE-COMMITMENT POSTCARDS: If you're randomized to this group, you will fill out postcards about why you want to be more active and will mail them back to us during the incentive period. Then, we will mail these postcards back to you during the habit maintenance period (weeks 13-24).

At Weeks 12 and 24, you will complete follow-up surveys that are very similar to the baseline survey.

Trial Weeks 13-24: HABIT MAINTENANCE. After Week 12, you will no longer have step goals or receive incentives. You are encouraged to continue to increase your physical activity or to maintain your

increased physical activity levels from the incentives period. You will take a third survey at Week 24 that will be similar to the Week 12 follow-up survey. You may keep your Fitbit device.

> **REQUEST FOR ADVICE:** If you're randomized to this group, we will ask you to write down some advice you have for Veterans about increasing your physical activity. Please mail us your advice in the prepaid envelope after Week 12.

After Week 24: PHONE INTERVIEW. After Week 24, we may ask you to participate in a one-time phone interview, which may take up to an hour. If you are contacted, you may decline to participate. The purpose of these interviews is to understand participants' experiences being in the study, their motivations, and how they felt about the incentives and study procedures. Some examples of questions that will be asked during the phone interview are, "Was the incentive, gift or prize unhelpful regarding your physical activity?" and "Did anything make participating in the study difficult?" You may refuse to answer any questions that you do not wish to answer.

We will audio record the phone interviews. This recording will be transcribed (written down word for word) so that approved study staff members will be able to review the responses as part of the data collected for the study. The recording may be reviewed by approved study staff during data analysis to make sure that the transcript accurately captured what was said and how it was said.

Throughout the study, we may contact you through mail or telephone calls about your participation in the study. The research records created from this study will include survey data, phone interviews, step counts, and some demographic data from your medical record. In addition to the study measures, we may also review your medical chart for any safety concerns about being in this study. We also want to ensure that we collect the correct information about your health to confirm your medical diagnoses and treatments and validate study results. We may gather information from inpatient stays, outpatient office visits, diagnoses, lab tests and imaging, billing records, and pharmacy records.

All of the study procedures will be conducted virtually (from your home), including Informed Consent.

4. What are some risks of joining this research study?

The procedures may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. If any of the risks included in this Consent Form become significantly updated during this study, we may ask you to sign an updated Consent Form to document that this new information has been explained to you. You will have the right to decide either to continue with the research study or to withdraw.

Below are study-related risks that are known at this time:

- **Privacy.** There is a risk of a breach of confidentiality. We will protect all identifying health care information with great care. We have extensive measures in place to keep this from happening and expect these measures to protect your personal information (as outlined in Section 7).
    - **Smartphone.** If you have an Android phone, you will initially need to allow the Fitbit app to access parts of your smartphone or Google Play account, including your camera, contacts, location, phone, SMS and storage. After downloading, we will tell you how to remove these permissions. However, you will need to keep location permissions turned on or turn them on when syncing. Fitbit may have access to your location data, including GPS signals, device sensors, Wi-Fi access points, and cell tower IDs. You may turn off your location at any time throughout the day. If you use an Android smartphone, you must have location data turned on when you're syncing your Fitbit.
    - **Audio-recording.** If you participate in the phone interview, we will not include your name or any identifying information on the recording. However, the sound of your voice is considered a personal identifier. This means that if someone acquires the recording, they may be able to identify you. You will be given an opportunity to review the recordings and erase any portions you are not comfortable with. The recording will be erased from the recorder after it has been transferred electronically to a secure VA server. Our methods of securing your privacy and confidentiality are described in Section 7.
    - **Survey.** The online survey is administered through a program called Qualtrics XM. The QualtricsXM program will have access to participant text/email, first name and first initial of the last name. Survey responses will be recorded within the QualtricsXM program.
    - **DocuSign.** This is an online electronic signature program licensed by the VA. DocuSign will have access to your name and email address. This information is required to use the programs.

- **Mobile data charges.** While the Fitbit app is free, downloading the app may use mobile data if you do not have a Wi-Fi connection. You may incur charges from your cell phone service provider for exceeding data usage plan allowances.

- **Health risk.** Increasing your physical activity may pose health risks. Walking more than you are used to may cause muscle/joint pain and increase your risk of injury or falling. Pay attention to how you feel as you start walking more. Think about how you can minimize your risk of injury by slowly working on endurance, strength, balance and flexibility.

  Your safety is important to us! Stop exercising if something hurts or you develop new symptoms you haven't discussed with your doctor. Stop exercising and talk to your doctor if you develop or experience:

    - Dizziness or shortness of breath
    - Chest pain or start to have a racing heart
    - Blood clot
    - Fever or infection

- Unplanned weight loss
- Foot/ankle sore that will not heal
- Joint swelling
- Recent surgery
- Hernia
- Recent leg, hip, or back injury

Discussing these symptoms with your doctor is important. You may contact study staff at any time with any concerns you have about your walking progress.

- **Survey or interview questions.** During the surveys or possible phone interview, you may feel uncomfortable answering some questions. You may choose not to answer any question you do not wish to answer.

- **Confidentiality.** We will keep your participation in the study confidential. There is the risk that a breach of confidentiality could occur; however, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized study staff as needed to conduct this study.

5. What are some benefits of joining this research study?

You may not receive a direct personal benefit by participating in the study. You may benefit from increasing your physical activity and overall living a healthier lifestyle. The study will help us learn how physical activity is affected by different types of incentives. This information can help us better design physical activity programs in the future.

6. Are there other ways I could receive these benefits?

You may choose to increase your physical activity in other ways without participating in this research study.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members

- VA Health Services Research & Development Service
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research)
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department, Internal Revenue Service, Austin Payment Center, and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- Fitbit, Inc. (owned by Google)
- Qualtrics XM
- DocuSign

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

The data that we collect for this study will be kept confidential. Your name and other identifying information will be kept in a secure password protected database. Your social security number will be stored in a separate, secure folder so study payments can be processed. Study data will be stored in a password-protected folder on the secure VA network and will only be accessed by approved study team members. Any paper records will be stored in locked file cabinets accessible only to study staff.

If you are contacted to participate in the study phone interview, and if you decide to participate, we will use an audio recorder to record your responses. This recording will be used for study staff to create a transcription, or a word-for-word text file, to make sure that your responses are recorded accurately. The audio recording and transcription files will be stored to a secure folder on the VA network and accessible only to study staff.

We will use the information that we collect for this study only for research purposes, not for profit. However, in the future, researchers may use this research information for the development of new ways to encourage physical activity in Veterans. Neither you nor your family will gain financially from discoveries made using the information you provide.

All audio-recordings will be kept in their entirety in accordance with VHA policy on quality assurance of records. Requests for amendment to the recordings will be documented in a transcribed version of the recording.

Since you will be using the Fitbit Inspire 2 and the Fitbit app, Fitbit (subsidiary of Google also known as Alphabet), will have access to your step counts, height and weight. Fitbit may also be able to access some of your personal information due to the permissions you allow when you download the app. If

you enter additional information into the app, this information will also be known to Fitbit and Google (Alphabet). We advise you to not enter any additional information into the app or change any of the app settings while participating in this study.

Once this study is completed, we will not use the study code linking you to your data (including any recordings and transcriptions) for any additional research. If you choose to enroll in the associated Rewards Research Repository, your data will be transferred to the repository prior to removing the study code. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

8. What are some other things to think about before I decide to join this research study?

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

All study compensation will be sent electronic funds transfer (EFT) if you have set this up with VA Puget Sound Health Care System. This process is frequently referred to as vendorization or being vendorized. This means paper checks will not be issued and all funds will be issued via direct deposit. Study staff will assist you with completing the necessary paperwork if necessary. You will not be paid or compensated for your research activities if you have not been vendorized.

You may earn up to $318 on average by participating in this study. As some incentives are lottery-based, there is a chance you could earn more. The $318 estimate includes $25 for the enrollment (consent visit), $25 for the Fitbit visit, $25 for each of the three surveys, and $25 if you participate in the study interview ($150 total). Additionally, you would earn an average maximum of $168 in incentives if you hit your daily step goal every day. Payments for the visits, the three surveys, and the interviews will be issued soon after you earn them. Incentives payments will be issued in bulk at the end of the incentives period.

Payments will either be made via direct deposit if you are vendorized with the VA or by electronic Amazon gift cards if you choose or cannot be vendorized. The payment (direct deposit) may take 16 weeks to reach you.

To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

To participate in this study, you must be able to install the Fitbit application on your phone. By doing so you will be agreeing to the terms of use and privacy policy of the Fitbit application.

You may need to complete a form so that the VA can send you study payments via direct deposit to your bank account. This would require that you mail us a form that includes your bank account information so that we can forward it to the VA fiscal department.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

The Principal Investigator and the study clinician may decide to terminate your participation in this study due to medical concerns.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

Neither VA Health Services Research and Development Service nor the VA is obligated to reimburse medical expenses due to your non-compliance with study procedures as described in this Consent Form or otherwise communicated to you by study personnel.

You do not waive any legal rights by signing this Consent Form.

11. What am I agreeing to by signing this form?

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____
Subject Signature Date

_____
Print Name of Subject

_____ _____
Staff Signature Date

_____
Print Name of Staff