VA MapTrek- Yr 2

IRB #: 201901762

Study Procedures

Approval Date: 2/15/2019

Table of Contents

Section 1.0- Project Overview

VA MapTrek is a mobile-phone-based web application that allows participants to take a virtual walk in interesting locations around the world while tracking their progress against the progress of other veterans on an interactive map. Steps are counted using a commercially-available triaxial accelerometer (e.g., Fitbit), and users see their progress overlaid on Google Maps. Our objective is to report activity levels to veterans, thereby encouraging them to walk more. Once participants know how to text and use Google maps, no additional training is needed. VA MapTrek does not require a special app, so there are no logins or passwords to remember. Simply registering one's Fitbit and mobile phone at an initial enrollment meeting suffices.

Section 1.1 Background Information

Nearly one-third of all veterans are obese, and an additional 44% are overweight. Obesity is a known risk factor for hypertension, coronary artery disease, type two diabetes, and multiple forms of cancer, all common medical problems affecting US veterans. Among veterans who are obese, 75% report the desire to lose weight, but 59% of these individuals are either inactive or irregularly active. Even moderate amounts of physical activity, e.g., 30 minutes of walking per day, can facilitate weight loss in overweight and obese individuals. Increased time walking is also associated with increased quality of life in all domains, including decreased depressive symptoms in older men. The prevalence of obesity and associated medical problems in veterans using VA services highlights the need for new interventions to help increase physical activity, specifically walking, among US veterans.

The VA has taken steps to improve health through lifestyle changes, specifically through the MOVE! Weight Management Program and the Whole Health Clinic. While proving to be successful, these programs require attendance at a VA location and only last for a finite period of time. Upon program completion, there is an unmet need to provide continued engagement. Ideally, the solution would be to offer a program suitable for long-distance deployment, especially to veterans living in rural areas. This program should also scale to expand in a cost-effective manner to serve veterans in all areas without requiring significant additions of personnel or increasing workloads in existing VA staff.
The goal of our study is to test the feasibility of using our new VA-specific version of MapTrek to incentivize veterans to engage in or maintain an active lifestyle.

VA MapTrek, an m-health intervention developed by collaborators at the University of Iowa, is a mobile-phone-based web app that allows users to take a virtual walk in interesting locations around the world while tracking their progress against that of others like themselves on an interactive map. Steps are counted by a commercially-available Fitbit triaxial accelerometer, and users see their progress overlaid on Google Maps. The objective is to report activity levels in the virtual environment to veterans, thereby encouraging them to first, walk more every day, and second, maintain these new increased levels of physical activity. Communication occurs via SMS text messaging, a ubiquitous communication medium. Using familiar technologies makes VA MapTrek easy to use. It does not require additional apps, logins, or passwords to remember. Registering a Fitbit and mobile phone during one appointment at a VA clinic allows play for the entire study.

Section 1.2 Research Questions

The purpose of the proposed project is to contribute to and improve upon the existing weight management and physical-activity-promoting programs available to veterans. Our specific objectives are to:

1) Assess the effectiveness of VA MapTrek as a whole to increase steps per day in veterans compared to the control group.
2) Assess the effectiveness of challenges within VA MapTrek to increase steps per day in veterans in the intervention group.
3) Identify additional areas of development within the MapTrek program to improve its future efficacy among veterans.

Section 1.3 Project Outline

All consented participants will be provided with a Fitbit and instructed to wear it all day, every day for the next 9 weeks (The first few participants may require an additional week or two of wear as we will not begin the first MapTrek race until we have at least 5 participants enrolled in the study. They will be told this upon enrollment.). We expect the enrollment process to take anywhere from 15 to 45 minutes, depending on group assignment and participant familiarity with using Fitbits.

This, plus an exit survey (given via text message or phone, whichever the participant prefers), will be the extent of participation for the control group.

Members of the intervention group will be instructed on how to use MapTrek, our virtual walking race, and will also be given an instruction packet to refer to later. Data collected during the first week from the Fitbit will be used to compute baseline activity level. This baseline data will be used to place participants into an appropriate initial race group. Participants are placed into groups with other individuals who are active at a similar level, so that groups will be competitive.

Each virtual walking race will begin on Monday morning and end on Saturday night. Results of each race will be announced on Sundays. Depending on their performance each week, group assignment may change. Participants will compete in 8 week-long races over the course of the study.

Participants will receive 2-4 text messages per day including a daily status report and a link to view the race. They will also periodically receive challenge messages. If a participant completes a challenge, they will be awarded bonus steps to help move them along the route quicker.

To win a race, a participant must be furthest along on the route at 11:59 pm on Saturday. There is a leaderboard within MapTrek that helps participants determine their standing within each race. Participants are allowed to choose the screen name displayed on the leaderboard so that they may remain anonymous if desired.

At baseline, we will collect the following data about all participants: first and last name, last 4 of social security number (for consent documentation and to look up records in CPRS), age, sex, race,

ethnicity, marital status, height, weight, body mass index, blood pressure, zip code, current medications, and comorbidities.

At the end of the study (9 weeks), we will collect the following data about all participants: height, weight, body mass index, blood pressure, current medications, and comorbidities.

At the end of the study (9 weeks), we will also contact participants via text message or phone call (based on their preference at baseline) to complete an exit survey. We anticipate this survey taking approximately 10 minutes to complete. We will attempt to contact all participants up to 3 times to complete the exit survey. If they cannot be reached, they will be considered lost to follow up.

Section 2.0- Participant Enrollment Procedures

Section 2.1 Consort Flow Diagram Data

Prior to enrolling any participants, we need to begin tracking the number of people who are eligible for our study, how many we contact, how many enroll, etc. To do this, make sure that you are filling out a Screening Survey in REDCap for anyone that is considered for enrollment in the study.

Section 2.2 Arrival at the Clinic

TBD

Section 2.3 Screening

Prior to enrolling participants, eligibility must be assessed. This may be done by asking the person or by screening CPRS first and then finishing the remaining questions with the potential participant. Everyone should be screened for:

1) Comfort speaking and reading in English (must be yes)
2) Age (must be 18-100 years)
2) Smartphone with text messaging and internet capabilities (must be yes)
3) Current Fitbit account (doesn't matter)
4) Male or Female (doesn't matter)
5) Current height (in inches) (You must indicate the date the height was measured/reported. If they are self-reporting it, put today's date; if it is from CPRS, indicate the date it was logged in CPRS)
6) Current weight (in pounds) (You must indicate the date the weight was measured/reported. If they are self-reporting it, put today's date; if it is from CPRS, indicate the date it was logged in CPRS)
7) BMI (REDCap will calculate, must be ≥ 25)
8) Text message or phone call exit survey preference (doesn't matter)
9) Record if the height/weight were self-reported or from CPRS
10) Determine if the potential participant is eligible
11) Indicate if they were randomized to the intervention group or control group
12) Include any relevant notes that we may need to know later

Section 2.4 Approaching the Patient

If you believe a patient is eligible for the study based on their CPRS data and discussions with the medical staff, approach the patient to see if they are interested in learning more and to finish any screening questions. You should only approach patients upon approval from the medical staff so that you don't disrupt clinic flow. Here is an example script (feel free to say in your own words as long as the major points are covered):

"We are conducting a study with eligible participants to see if our map-based race will encourage Veterans to take more steps per day. We will randomize the participants to 2 different groups, a control group and an intervention group. The control group will receive a Fitbit, which is a small device that is worn on your wrist that measures your movements, to wear for approximately 9 weeks. At the end of the 9 weeks, they will complete an exit survey via phone call or online.

The intervention group will also be given a Fitbit and asked to wear it for approximately 9 weeks, but they will also be enrolled in a map-based race. You will be notified about your progress in the race via text message and you may also receive challenges where you can earn extra steps in the race. At the end of the 9 weeks, they will also complete an exit survey that asks about their experiences with the study.

Is this something that you'd like to learn more about or might be interested in participating in?"

If the person indicates that they'd like to learn more about the study or want to participate, be sure to complete any remaining fields on the Screening Survey (Appendix A).

If any of these criteria are <u>not</u> met, the person is ineligible for the study. Please explain the reason for their ineligibility and thank them for their time.

If all criteria are met, you should continue on with the informed consent procedures in a room that is approved by the medical staff to avoid disrupting the clinic flow.

Section 2.5 Consenting Procedures

If the person is deemed eligible for the study and is still interested in participating, provide them with a copy of the Information Sheet for Research Subjects (Appendix B), the Informed Consent document (Appendix C), and the VA brochure about participating in research studies (not pictured) to follow along with while you explain the study. They may take these home with them for their records in case they need to refer to them at a later date.

First, explain the Information Sheet for Research Subjects (Appendix B). You do not need to read it word-for-word, but you should cover all major points on the document. The first 3 bullets cover reasons that they may not want to participate in the study, while the last bullet is a reason that they may want to. Give them time to read the document and answer any questions that they may have.

If they are still interested in the study, move on to the Informed Consent (Appendix C). Again, you do not need to read it word-for-word to the participant, but you should cover all sections, give them time to read it, and answer any questions that they may have.

<u>Note</u>: Be sure to get the correct spelling of the Participant's first and last name on the top of the first page of the Informed Consent as well as their date of birth and last 4 of the SS # on the bottom of the first page. You will need to transfer this information throughout the rest of the document after the patient leaves (see your example paperwork).

<u>Note</u>: Page 4 of the Informed Consent (Appendix C) has a place for the participant to initial Yes or No about us using their data in the future. One of these options must be initialed (not checked) by the participant. Answering No to this question does not prevent them from participating in the study.

Once the consent document has been discussed make sure that any remaining questions are answered. If the person still wants to participate, have them print, sign, and date our copy of the

informed consent document. Then, you will **SIGN AND DATE** the document as the person who obtained consent (this is very easy to forget).

Finally, be sure to give them the VA brochure (not pictured) about being a research participant and answer any questions about this document that they may have.

Section 2.6 Randomization Procedures

To determine which group the participant will be placed into, grab one folder from each pile (Intervention and Control) and let the participant choose one. If the folder contains the MapTrek instruction packet (Appendix D), they are in the intervention group. If the folder contains the fake paperwork, they are in the control group.

Be sure to note the group assignment in the Screening Survey and mark the survey as complete.

Section 2.7 Control Group Instructions

If the participant was assigned to the control group, the following tasks need to be completed before they leave the appointment:

1) Give the participant the Fitbit®. Instruct them on how to keep it charged and help them put it on for the first time.

2) Help the participant create a Fitbit® account by having them download the Fitbit® app from their app store and follow these steps:

1) Make sure their phone's Bluetooth is turned on.
2) Once the app is downloaded, open the app and click 'Join Fitbit'.
3) Choose 'Charge 3' as the Fitbit Tracker.
4) Click 'Set Up Your Fitbit Charge 3'
5) Click 'Let's Go'
6) Have them scroll up or down to their current height. Click 'Next'.
7) Select their gender by clicking on the appropriate picture. Click 'Next'.
8) Have them scroll left or right to their current weight. Click 'Next'.
9) Have them scroll left and right to input their birth date. Click 'Next'.
10) Have them enter their Full Name, Email Address, and Password. They will need to agree to the Terms of Service and Privacy Policy by clicking the check mark. Let them choose if they would like to receive news and promotions from the company.
11) Click 'Next' to get past the Terms of Service and Privacy Policy screen.
12) Let them Meet their Charge 3 by clicking 'Next' through the tutorial page.
13) You may need to plug the Charge 3 in to complete set up.
14) Make sure the Charge 3 is awake and close to the phone so that they can sync.
15) Once it syncs, it will ask for the 4-digit number of the Fitbit screen.
16) Click 'Next' and 'Done' to get through some tutorial information.
17) They will then be logged into the Fitbit app. They may have a warning that email verification is required. They can do this at a later time.
18) Show them that steps, distance, calories, and minutes of exercise are tracked on the dashboard.

3) Enroll the participant in the Control Group Boomerang Study by visiting https://vinci.cs.uiowa.edu/meditext2 . Even though they will not be using MapTrek, they need to be entered into the Boomerang Study so that we can obtain the data from their Fitbit®.

- Log in using your username and password
- Select VA FY19-20 Control from drop down menu
- Click on the Green "Enroll Patient" button in the top right corner
- Enter the participant's phone number, click Next
- Enter the Record ID for the participant from REDCap as the subject identifier (you do not need to enter an email address, Preferred Language should be kept as English for this study)
- Select "Go to registration page" and click Submit
- You will be taken to the Fitbit® screen and asked to provide the participant's Fitbit login information. Once they have entered their email and password, you need to select "Allow All" from the dropdown menu and click Allow. Once this is completed, their Fitbit will be synced with Boomerang
- Return to Boomerang, Click on the Patients tab, and select the Record ID for the patient you just enrolled
- Click the Green "Add Subscription" button in the top right corner
- Select "Fitbit Reminders" as the Protocol, "Today" as the start date, the Saturday date following the end of their 9 weeks of participation as the End Date, Frequency should be set to "1", allow the participant to choose the times they will receive reminders to wear/sync their Fitbit, uncheck both "Send end message" and "Send end email to managers", and click Submit
- From the home screen in Boomerang, make sure the subscription worked by clicking the Patients tab, selecting the patient, and clicking on the Subscriptions tab. Make sure the subscription is set up correctly

4) Have the participant put the Fitbit® on now and instruct them to continue wearing it every day until the 9 weeks are finished (unless they are bathing, swimming, or sleeping).

5) Remind them they will receive either a text message or a phone call to complete the exit survey at the end of the study.

Once these tasks have been completed, the participant is free to leave.

Section 2.8 Intervention Group Instructions

If the participant was assigned to the intervention group, the following tasks need to be completed before they leave the appointment:

1) Give the participant the Fitbit®.

2) Help the participant create a Fitbit® account by having them download the Fitbit® app from their app store and follow these steps:

1) Make sure their phone's Bluetooth is turned on.
2) Once the app is downloaded, open the app and click 'Join Fitbit'.

3) Choose 'Charge 3' as the Fitbit Tracker.
4) Click 'Set Up Your Fitbit Charge 3'
5) Click 'Let's Go'
6) Have them scroll up or down to their current height. Click 'Next'.
7) Select their gender by clicking on the appropriate picture. Click 'Next'.
8) Have them scroll left or right to their current weight. Click 'Next'.
9) Have them scroll left and right to input their birth date. Click 'Next'.
10) Have them enter their Full Name, Email Address, and Password. They will need to agree to the Terms of Service and Privacy Policy by clicking the check mark. Let them choose if they would like to receive news and promotions from the company.
11) Click 'Next' to get past the Terms of Service and Privacy Policy screen.
12) Let them Meet their Charge 3 by clicking 'Next' through the tutorial page.
13) You may need to plug the Charge 3 in to complete set up.
14) Make sure the Charge 3 is awake and close to the phone so that they can sync.
15) Once it syncs, it will ask for the 4-digit number of the Fitbit screen.
16) Click 'Next' and 'Done' to get through some tutorial information.
17) They will then be logged into the Fitbit app. They may have a warning that email verification is required. They can do this at a later time.
18) Show them that steps, distance, calories, and minutes of exercise are tracked on the dashboard.

3) Enroll the participant in MapTrek by visiting https://vinci.cs.uiowa.edu/maptrek2/admin/

- Log in using your username and password
- Basic Strategy: start at the bottom of the screen and work your way up
- On the Home Screen, right click on the 'Change' next to Player Icons, choose 'Open link in new tab'
- Using the 4 categories (animals, military, outdoors, other), help the participant choose an icon
- Navigate back to MapTrek and click 'Add' next to 'Players'
- Have the participant choose a username (**Note**: inform them that this username will be visible by others, so they should make it something that is non-identifiable if they wish!)
- Enter the participant's phone number
- Have the participant choose the earliest and latest times that they wish to receive text messages
- Use the Notes field for any information you may want to remember about the person (that is not HIPAA sensitive)
- Choose the requested icon from the dropdown menu
- Click 'Save'
- Click 'Add' next to League Participants
- Choose the player from the dropdown menu
- Choose the VA FY19-20 Intervention league from the dropdown
- Make sure 'Active' is not selected
- Click 'Save'

- Click on the words 'User fitbits'
- Click on 'Associate New User Fitbit' in the top right corner
- Choose the participant from the dropdown menu, click 'Authentic with Fitbit'
- You will be taken to the Fitbit® screen and asked to provide the participant's Fitbit login information. Once they have entered their email and password, you need to select "Allow All" from the dropdown menu and click Allow. Once this is completed, their Fitbit will be synced with MapTrek

4) Give the participant the MapTrek Instruction Packet (Appendix D). Talk through each slide of the instructions and answer any questions that the participant has.

5) Have the participant put the Fitbit® on now and instruct them to continue wearing it every day until the 9 weeks are finished (unless they are bathing, swimming, or sleeping).

6) Remind them they will receive either a text message or a phone call to complete the exit survey at the end of the study.

Once these tasks have been completed, the participant is free to leave.

Section 2.9 Data Entry Procedures

Once the participant has left, you need to complete 3 REDCap surveys- Baseline Participant Info (Appendix E), Baseline Medications (Appendix F), and Baseline Comorbidities (Appendix G). The necessary information will come from your discussion with the participant and CPRS.

Section 2.10 Storing the Files

When you are done working in the clinic for the day, all of the participant informed consent forms/HIPAA authorization forms must be taken to the annex at UIHC to be stored in the locked cabinets.

Note: Be sure you have your Authorization to Transport form with you before you transport any forms off of the VA campus!

Section 2.11 Submitting Payments

Once a participant has completed the exit survey, they need to be compensated. Open the PaymentTemplate_MapTrekFitbitGame file using the following path: rdss_lpolgree > MapTrek Pilot > FitbitGame > Payments.

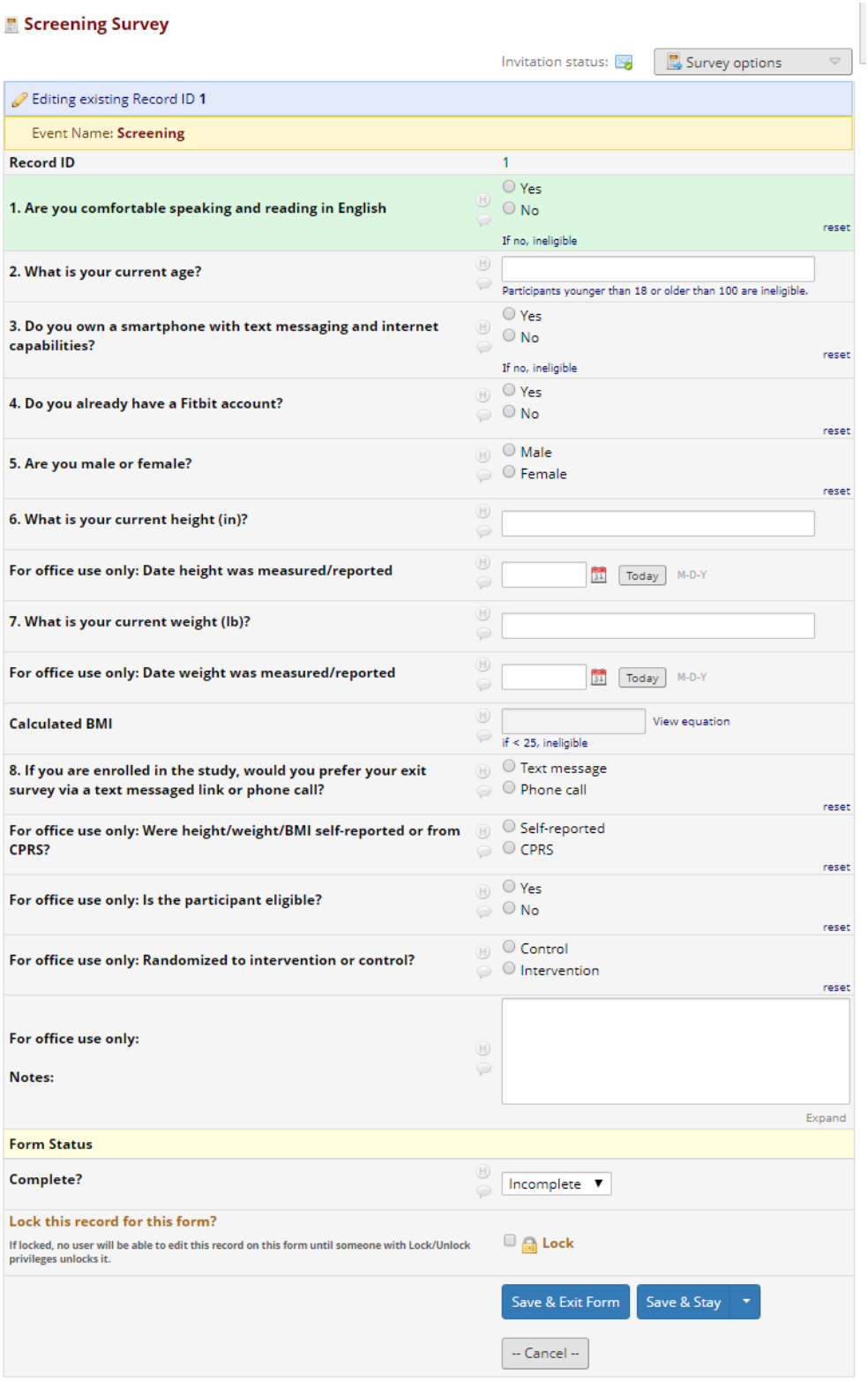
Create a new file by clicking "Save As" and re-naming the file using the following the date the payment was submitted to eVouchers (example: 01.29.2019.xlsx).

Complete the spreadsheet by copying and pasting the participant's information from the ParticipantInfo_MapTrekFitbitGame spreadsheet. You can include multiple participants in this spreadsheet before submitting.

Instructions on how to submit the payment are found in Payment Procedures file listed under rdss_lpolgree > MapTrek Pilot > FitbitGame > Payments.

Appendices

Appendix A



Screening Survey

Invitation status: Survey options

Editing existing Record ID **1**

Event Name: **Screening**

Record ID	1
1. Are you comfortable speaking and reading in English	○ Yes ○ No reset If no, ineligible
2. What is your current age?	Participants younger than 18 or older than 100 are ineligible.
3. Do you own a smartphone with text messaging and internet capabilities?	○ Yes ○ No reset If no, ineligible
4. Do you already have a Fitbit account?	○ Yes ○ No reset
5. Are you male or female?	○ Male ○ Female reset
6. What is your current height (in)?	
For office use only: Date height was measured/reported	Today M-D-Y
7. What is your current weight (lb)?	
For office use only: Date weight was measured/reported	Today M-D-Y
Calculated BMI	View equation if < 25, ineligible
8. If you are enrolled in the study, would you prefer your exit survey via a text messaged link or phone call?	○ Text message ○ Phone call reset
For office use only: Were height/weight/BMI self-reported or from CPRS?	○ Self-reported ○ CPRS reset
For office use only: Is the participant eligible?	○ Yes ○ No reset
For office use only: Randomized to intervention or control?	○ Control ○ Intervention reset
For office use only: **Notes:**	Expand
Form Status	
Complete?	Incomplete
Lock this record for this form? If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.	Lock

Save & Exit Form | Save & Stay

-- Cancel --

Appendix B

FOR IRB USE ONLY
APPROVED BY: IRB-03 VA Only
IRB ID #: 201901762
APPROVAL DATE: 02/08/19

INFORMATION SHEET FOR RESEARCH SUBJECTS

Research Study Title: VA MapTrek, an M-Health Intervention to Increase Steps per Day in Rural Veterans
Principal Investigator: Philip Polgreen

This sheet provides key information you need to know about participating in this research study. Taking part in a research study is voluntary. You don't need to take part in this study to receive care for your condition. You can stop taking part in this study at any time without any penalty. Feel free to ask the researchers any questions you have about this study. The full informed consent document includes detailed information about the study.

The purpose of the research study: To find out if our virtual walking race, VA MapTrek, is effective at increasing the number of steps taken per day by Veterans.

Main procedures you will undergo if you take part in this research study: You will be randomized to either the Fitbit only group or the Fitbit + VA MapTrek group. You will be given a Fitbit, shown how to use it, and asked to wear it every day for 9 weeks. After 9 weeks, you will be asked to complete a survey about your experiences. Data will be collected from your medical record at both the beginning and end of the study.

If you are in the Fitbit + VA MapTrek group, you will also participate in our virtual walking race, VA MapTrek for 8 of the 9 weeks.

Number study visits and how long study visits will be: There will be 1 in-person visit to enroll you in the study (15 – 45 minutes). The rest of the study will take place via text message or phone call.

How long you will be in the study: Your total participation in the study will be 9 weeks.

Reasons why I may or may not want to participate in this study:

- You may be randomized to the group that you did not want to be in.
- We will collect information about you from your VA medical record.
- You will need to be familiar enough with technology to keep your Fitbit charged, sync your Fitbit to your smartphone, and read text messages.
- You may want to help the research team determine if our race can help Veterans be more physically active.

Main risks of taking part in this research study: Possible injury from being more physically active than usual.

Possible benefits of taking part in this research study: You probably won't benefit greatly from participating in this study.

Appendix C

FOR IRB USE ONLY
APPROVED BY: IRB-03 VA Only
IRB ID #: 201901762
APPROVAL DATE: 02/08/19
EXPIRATION DATE: 02/08/20

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name:

Title of Study: VA MapTrek- Yr2

Principal Investigator: Philip Polgreen, MD **VAMC:** Iowa City, Iowa

INFORMED CONSENT DOCUMENT

Project Title: **VA MapTrek, an M-Health Intervention to Increase Steps per Day in Rural Veterans**

Principal Investigator: Philip Polgreen

Research Team Contact: **Shelby Francis, 319-678-8037**

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a VA patient that is at least 18 years of age, is comfortable speaking and reading in English, has a smart phone with texting and internet capabilities, and has a BMI of 25 or greater.

The purpose of this research study is to assess if our virtual walking race, VA MapTrek, is effective at increasing number of steps taken per day by Veterans.

SUBJECT'S IDENTIFICATION (I.D. plate or give name-last, first, middle)

VA FORM APR 1991 (RS) 10-1086

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 376 people will take part in this study conducted by investigators at the Iowa City VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 9 weeks.

The initial visit will last between 15 and 45 minutes. We will register you for the Fitbit app and show you how to use the Fitbit. For 9 weeks, you will wear the Fitbit every day. Once you are done wearing the Fitbit, we will collect survey data from you via text message or phone call. This should take approximately 10 minutes.

You should review the third party End User Agreement (EULA) used as part of the study prior to agreeing to participate.

WHAT WILL HAPPEN DURING THIS STUDY?

Overview:

We will collect activity measurements from the Fitbit in 1-minute intervals for 9 weeks. We will collect your first and last name as well as the last 4 digits of your social security number from you for identification purposes. We will collect the following information from you or your VA medical record (CPRS) at baseline: age, sex, race, marital status, height, weight, body mass index, blood pressure, zip code, current medications, and comorbidities. We will collect height, weight, body mass index, blood pressure, medications, and comorbidities again at 9 weeks.

At the end of 9 weeks, we will collect survey responses from you via text message or phone call, whichever you prefer. This survey asks for feedback about your study experience. You are free to skip any questions that you prefer to not answer. We will collect the medical information listed above.

Details:

First, you will be randomized into either the Fitbit only group or the Fitbit + VA MapTrek group. This means the study group will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of being assigned to either study group.

Those in the Fitbit only group will only complete the activities described above.

For those randomized to the Fitbit + VA MapTrek group, each race will begin on Monday morning and the winners and final standings will be declared on Sunday afternoon. You will participate in 8 week-long races over the course of the study.

Each day, those in the Fitbit + VA MapTrek group will receive between 2 and 4 automatically generated text messages including a daily status report and possibly a challenge. If you complete a challenge, you will be awarded a pre-specified number of bonus steps that will speed you along the route. Challenges will focus on increasing the number of steps you take per day.

Winning each week-long race entails being the furthest along on the route when the race ends each Saturday night at 11:59 pm. The leaderboard and map will provide an accounting of each participant's performance.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding how to increase physical activity in Veterans, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team.

However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored *with a code which may be linked to* your name. If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Philip Polgreen at 319-384-6194. However, if some research with your data has already been completed, the information from that research may still be used.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be used for future research.

_____ Yes _____ No

We may contact you in the future about participating in one of our future studies. We will store your name and phone number to contact you in the future. Agreeing to participate in the current study does not obligate you to participate in any future studies. You will be asked to sign a new consent form for any future studies.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The only foreseeable risks of this study are possible injury as a result of being more physically active than usual as well as loss of confidentiality of data.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the knowledge gained in determining if a virtual walking race can motivate Veterans to walk more.

Subject Name:

Title of Study: VA MapTrek- Yr2

Principal Investigator: Philip Polgreen, MD **VAMC:** Iowa City, Iowa

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs beyond the use of your usual smart phone text messaging and data plan for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

You will be allowed to keep your Fitbit once the study is complete.

WHO IS FUNDING THIS STUDY?

The US Department of Veterans Affairs, Office of Rural Health is funding this research study. This means that the Iowa City Veterans Administration is receiving payments from the US Department of Veterans Affairs, Office of Rural Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the US Department of Veterans Affairs, Office of Rural Health for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Iowa City VA Health Care System
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

Subject Name:

Title of Study: VA MapTrek- Yr2

Principal Investigator: Philip Polgreen, MD **VAMC:** Iowa City, Iowa

To help protect your confidentiality, we will store all electronic data we collect from you on a secure server that can only be accessed by the research team. Paper forms will be kept in a locked cabinet in the research team's locked office. If we write a report or article about this study or share the study data set with others, we will do so in a way that you cannot be directly identified.

A copy of the Informed Consent Document will be placed in your medical record.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we ask that you contact us at 319-467-8166 or pharm-maptrek-pilot@uiowa and leave us a message that you would like to drop out of the VA MapTrek study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: the research interns at 319-467-8166. If you experience a research-related injury, please contact: Philip Polgreen at 319-384-6194.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. A copy of the VA brochure 'Volunteering in Research,' (found at http://www.research.va.gov/programs/pride/veterans/Volunteering-in-Research.pdf) has been provided to the prior to signing this informed consent document. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Subject Name:

Title of Study: VA MapTrek- Yr2

Principal Investigator: Philip Polgreen, MD **VAMC:** Iowa City, Iowa

RESEARCH SUBJECT'S RIGHTS

I have read or have had read to me all of the above. A member of the research team has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.

I have been told that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The Iowa City VA Health Care System is available to provide necessary medical treatment for any injury resulting from participation in this research study. I have been told that I will not be required to pay for care received as a subject in this study except in accordance with federal law (Title 38 United States Code 1710(f) and 1710(g)) and that certain veterans are required to pay co-payments for medical care and services provided by the VA.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

_____ _____

Subject's Signature Date

Subject Name:

Title of Study: VA MapTrek- Yr2

Principal Investigator: Philip Polgreen, MD **VAMC:** Iowa City, Iowa

As the subject's Legally Authorized Representative I have been told that my obligation is to try to determine what the subject would do if he/she were competent. If I can't determine what the subject's wishes would be, I have been told that by obligation is to do what I think would be in the subject's best interest.

_____

Signature of Subject's Authorized Representative* Date
*Required only if subject is not competent

_____

Subject's Representative & Relationship (print)

STATEMENT OF PERSON WHO OBTAINED CONSENT

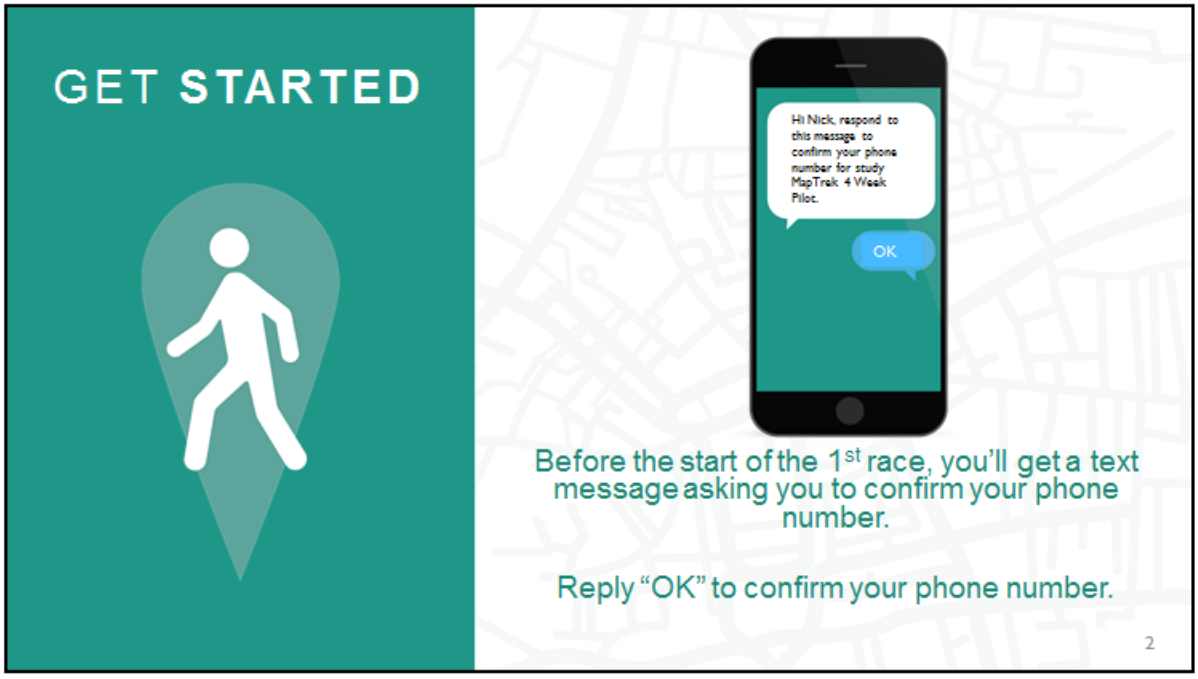
I have discussed the above points with the subject or, where appropriate, with the subject's authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

Signature of Person who Obtained Consent Date

Appendix D


VA MAPTREK


GET STARTED
Hi Nick, respond to this message to confirm your phone number for study MapTrek 4 Week Pilot.
OK
Before the start of the 1st race, you'll get a text message asking you to confirm your phone number.
Reply "OK" to confirm your phone number.
2

GET **STARTED**

On the 1st day of every race, you'll get a text message with a link to the route's location.

Throughout the race, you may receive additional messages if you forget to sync or wear your Fitbit®.

3

SYNCING YOUR FITBIT:

At least once per day, open the Fitbit® app on your phone and drag the screen down. This will sync your Fitbit® to the app and advance your character along the route.

Tip: Turn on "all-day sync" in the Fitbit® app on your phone, this will also help keep your progress along the route current.

4

THE RACE

GET MOVING

Steps recorded by your Fitbit® will move your character along a route on a map.

During the race, you will receive daily text messages.

Click the link in the text messages to display the following features:

The Route Leaderboard Street View

5

THE ROUTE

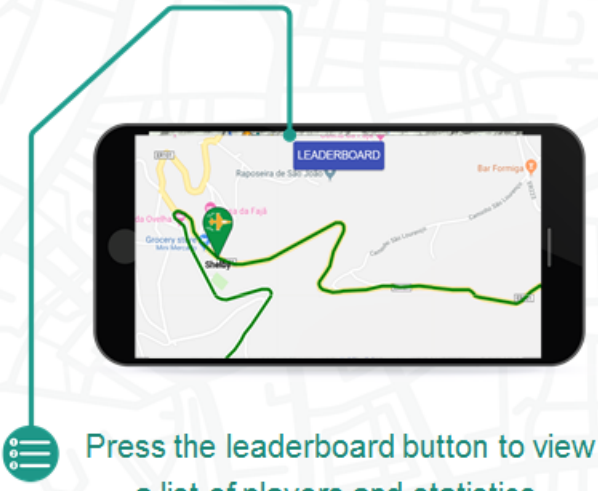
The route is indicated by a line on the map.

You are represented by an icon and your chosen username.

You can zoom in and out on the map to see other players' locations along the route.

6

LEADER **BOARD**



Press the leaderboard button to view a list of players and statistics.

7

LEADER **BOARD**

The leaderboard will show your progress compared to the other players in the race.

8

RACE **CHALLENGES**

You may periodically receive challenges.

A fulfilled challenge will move your character along the route by the number of bonus steps awarded.

9

MAPTREK **NOTES**

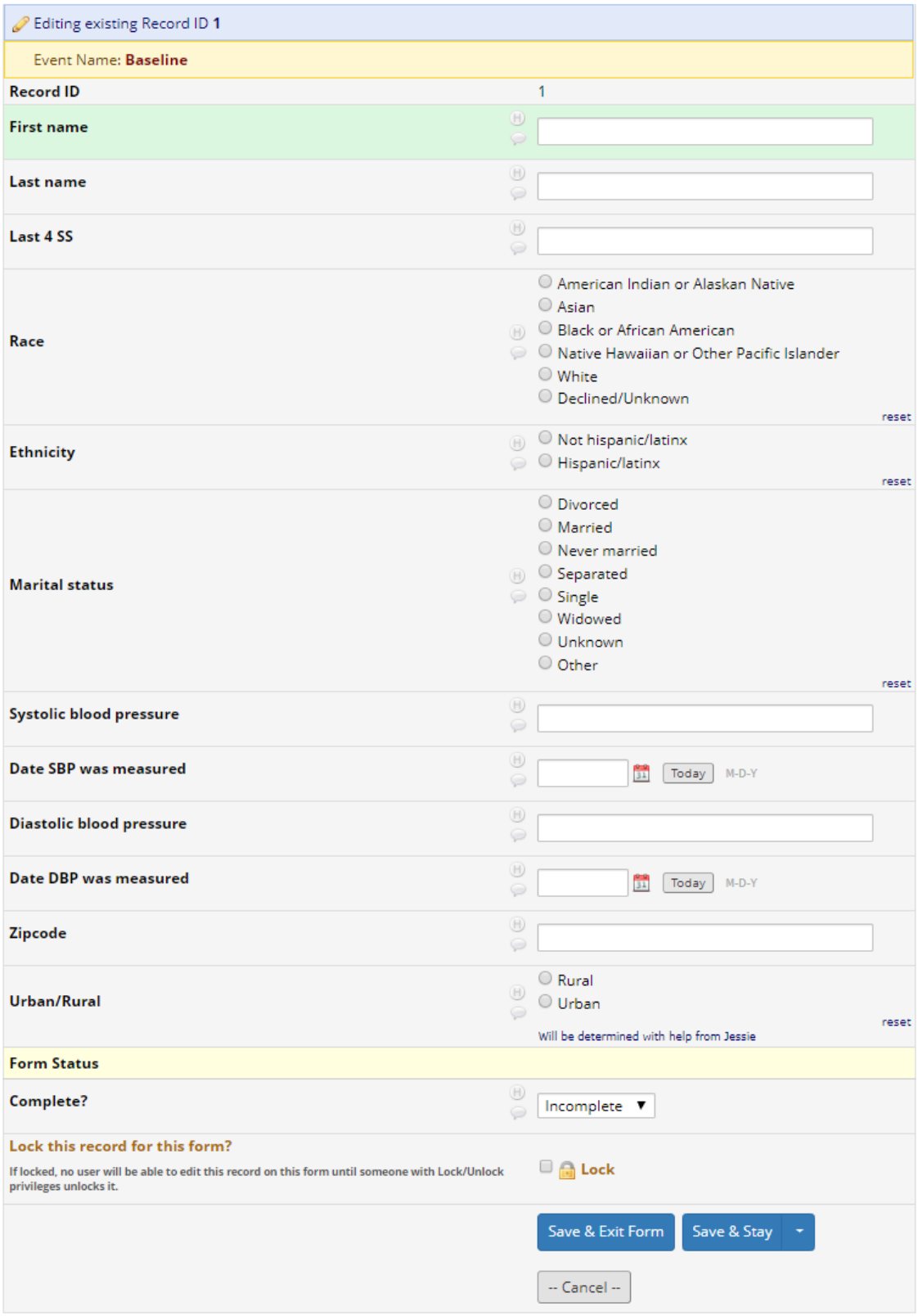
If you have any questions or problems throughout the study, text "Support" with a brief description of your problem and we will contact you ASAP.

In the unlikely event that you wish to immediately stop receiving communication from MapTrek, text "Support" followed by a separate text message with only the word "Stop".

10

Appendix E

Baseline Participant Info



Editing existing Record ID **1**

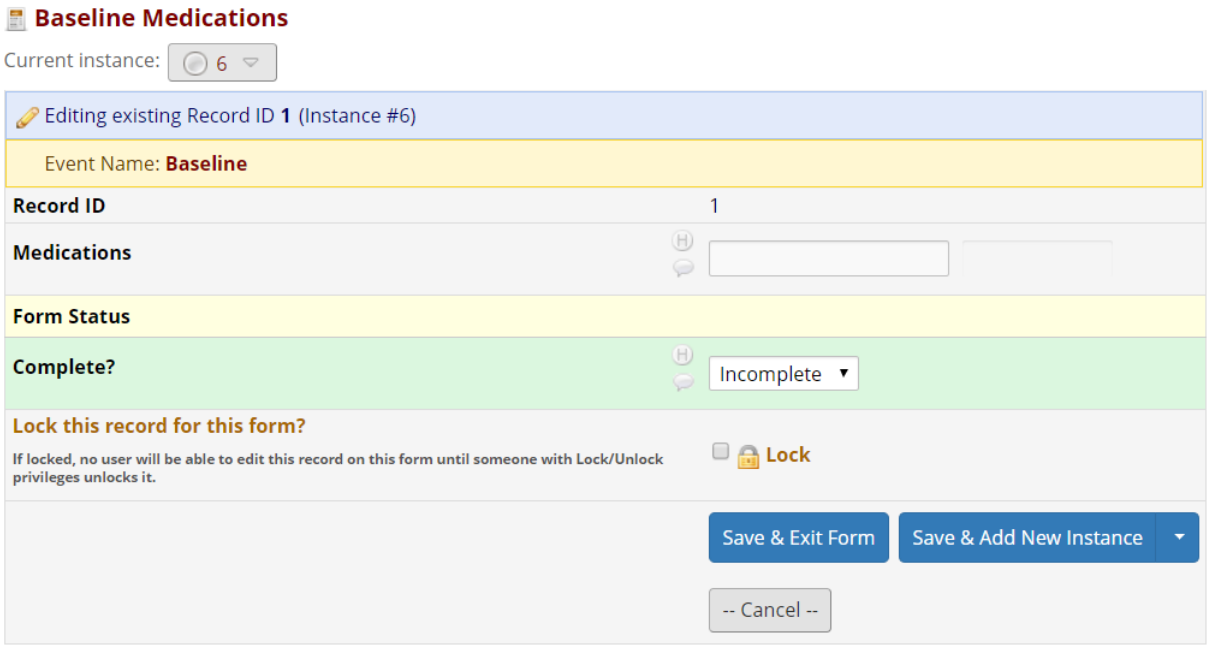
Event Name: **Baseline**

Record ID	1
First name	
Last name	
Last 4 SS	
Race	○ American Indian or Alaskan Native ○ Asian ○ Black or African American ○ Native Hawaiian or Other Pacific Islander ○ White ○ Declined/Unknown reset
Ethnicity	○ Not hispanic/latinx ○ Hispanic/latinx reset
Marital status	○ Divorced ○ Married ○ Never married ○ Separated ○ Single ○ Widowed ○ Unknown ○ Other reset
Systolic blood pressure	
Date SBP was measured	Today M-D-Y
Diastolic blood pressure	
Date DBP was measured	Today M-D-Y
Zipcode	
Urban/Rural	○ Rural ○ Urban reset Will be determined with help from Jessie
Form Status	
Complete?	Incomplete ▼
Lock this record for this form? If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.	☐ Lock

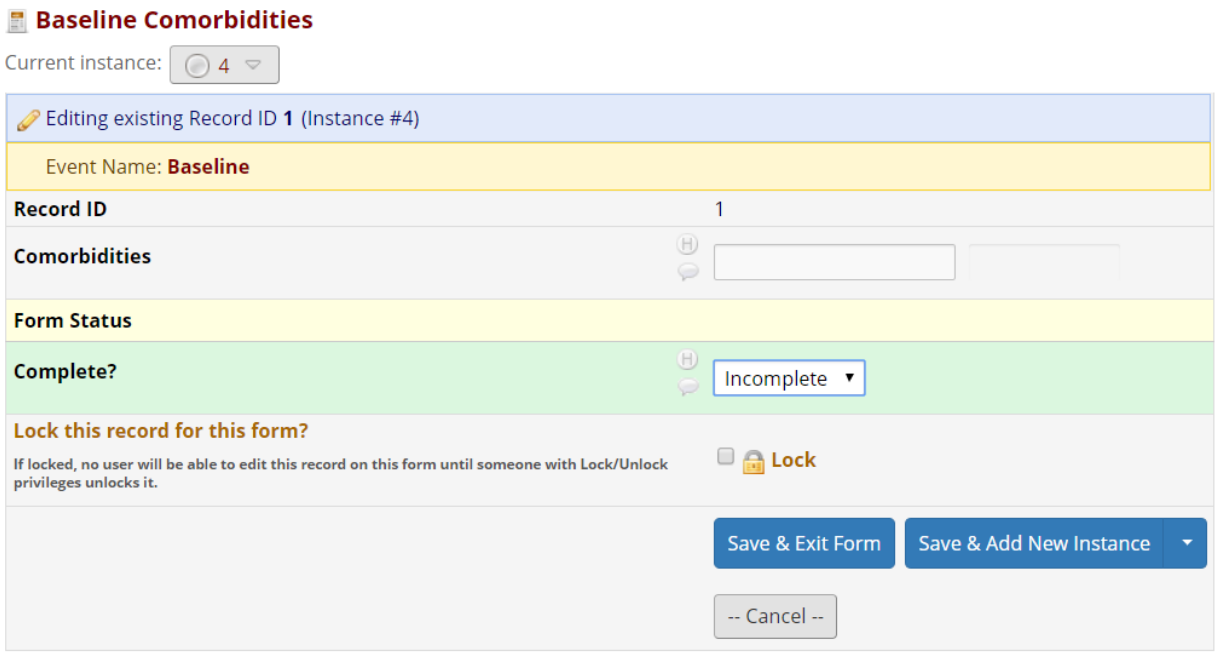
Save & Exit Form | Save & Stay

-- Cancel --

Appendix F


Baseline Medications
Current instance: 6
Editing existing Record ID 1 (Instance #6)
Event Name: Baseline
Record ID
1
Medications
Form Status
Complete?
Incomplete
Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.
Lock
Save & Exit Form
Save & Add New Instance
-- Cancel --

Appendix G


Baseline Comorbidities
Current instance: 4
Editing existing Record ID 1 (Instance #4)
Event Name: Baseline
Record ID
1
Comorbidities
Form Status
Complete?
Incomplete
Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.
Lock
Save & Exit Form
Save & Add New Instance
-- Cancel --