**IRB TEMPLATE FOR WAY TO HEALTH STUDIES**

General IRB Outline template

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Sample IRB protocol using Way to Health

A Randomized, Controlled Trial Evaluating Methods to Increase Physical Activity After Hospitalization for Myocardial Infarction

**1. Abstract**

* ~200 words
* Explain background significance, what is still unknown
* Touch on any behavioral economics insights that have been previously tested or are novel approaches that you plan to use
* Add 1-2 sentences about study objectives

Example:

Cardiovascular disease is the leading cause of mortality in the United States. Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality. However, despite CR being a Class I (standard of care) recommendation in multiple American Heart Association AMI guidelines, more than 80% of eligible patients do not receive appropriate CR and much of this is due to challenges in access to these programs. Recent innovations in technology allow us to passively monitor an individual’s physical activity using wearable devices. Incentives designed using insights from behavioral economics have been demonstrated to motivate device engagement and behavior change. A remotely-monitored CR program could improve access for many individuals and potentially be more cost-effective because it is less resource- and personnel-intensive. The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity. Participants will go through four phases: baseline period (weeks X-X), ramp-up period (weeks X-X), maintenance period (weeks X-X), and follow-up period (weeks X-X).

**2. Overall objectives**

The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity

**3. Aims**

 *3.1 Primary outcome*

The primary outcome variable is the change in mean daily step count from the baseline period (weeks X-X) to the maintenance period (weeks X-X).

 *3.2 Secondary outcome*

Secondary outcomes include change in mean daily steps from baseline to follow-up period, change in time slept from baseline to maintenance period, change in six minute walk test from baseline to end of maintenance period (optional for participants), and healthcare utilization during the ramp-up and maintenance period as measured by number of hospitalizations and emergency department visits.

**4. Background**

Cardiovascular disease is the leading cause of mortality in the United States (1). Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality (2). Patients completing CR have also been found to have improvements in blood pressure control, lipid levels, and a reduction in smoking (3).

Despite this, more than 80% of eligible patients do not receive cardiac rehabilitation (4). Access and affordability are some of the primary factors associated with the low compliance with CR (5). Since CR centers are often located in more urban areas, patients that live in more rural locations or without transportation may have difficulty reaching these centers.

Recent innovations in technology allow us to passively monitor an individual’s physical activity using wearable devices (6). These devices have been demonstrated to be accurate for tracking step counts (7) and could be utilized to deploy a home-based intervention. Recently, the concept of a remotely-monitored, internet-based CR program has been shown to be safe and superior to usual care (in terms of reducing CVD risk) in a small Canadian pilot study (8). A remotely-monitored CR program would provide access for the many individuals that cannot reach a CR center and potentially, in the future, could be more cost-effective because it is less resource- and personnel-intensive. The optimal range of steps for secondary prevention of AMI is in the range of 6500-8500 steps/day (9).

[1] Murray et al, US Burden of Disease Collaborators. The State of US Health, 1990-2010. JAMA. 2013;310(6):591-608. [2] Lawler PR, Filion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation postmyocardial infarction: a systematic review and meta-analysis of randomized controlled trials. Am Heart J 2011;162:571–84.e2.[3] Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med 2004;116:682–92. [4] Menezes AR, Lavie CJ, Milani RV, et al. Cardiac rehabilitation in the United States. Prog Cardiovasc Dis 2014;56:522–9. [5] Sandesara PB, Lambert CT, Gordon NF, Fletcher GF, Franklin BA, Wenger NK, et al. Cardiac rehabilitation and risk reduction. Time to “rebrand and reinvigorate.” JACC. 2015;65(4):389-395. [6] Patel MS, Asch DA, Volpp KG. Wearable devices as facilitators, not drivers, of health behavior change. JAMA. 2015;313(5):459-460. [7] Case MA, Burwick HA, Volpp KG, Patel MS. The accuracy of smartphone applications and wearable devices for tracking physical activity data. JAMA. 2015;313(6):625-626. [8] Lear S, Singer J, Banner-Lukaris D, et al. Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet. Circ Cardiovasc Qual Outcomes. 2014;7(6):952-959 [9] Ayabe M, Brubaker PH, Dobrosielski D, Miller HS, Kiyonaga A, Shindo M, Tanaka H. Target step count for the secondary prevention of cardiovascular disease. Circ J. 2008;72(2):299-303.

**5. Study design**

 *5.1 Design*

We will conduct a two-arm randomized, controlled trial comparing a control group that uses a wearable devices to track physical activity and sleep data to an intervention group that uses the same wearable devices and receives a financial incentive to adhere to a step goal program. Patients will be randomized to one of the two arms using a block size of four (Include randomization scheme- blocked, blocked with stratification, etc.). To account for possible differences in reimbursement for CR among patients with and without Medicare, we will stratify the randomization by age (less than 65 years vs. 65 years and older). Since referral to a standard health system CR program is recommended for all patients after an acute myocardial infarction, we will not attempt to modify current referral and adherence patterns to these programs. However, data suggest that more than 80% will not actually obtain this type of cardiac rehabilitation. During the study, we will ask all patients whether or not they participated in a standard cardiac rehabilitation program.

All participants will receive $X for enrolling and $X for completing the X week study (Indicate any financial incentives that that participant will receive and what they need to complete to be paid). All participants will be given the option to have an in-person visit with the study coordinator at the beginning and after the maintenance period to conduct the six minute walk test. If a participant chooses to participate they will receive $X for each visit.

Participants in all arms will be informed of the CDC/federal recommendation guidelines for physical activity and receive additional interventions as follows:

Arm 1. Control: use a wearable device to track physical activity and sleep data. Receive reminders to use their device and sync their data.

Arm 2. Financial incentive-based program: Participants will be given a wearable device to monitor daily step counts and sleep patterns with automated feedback on physical activity goal attainment via text message, automated interactive voice call or email (based on participant communication choice). Based on recommendations for the optimal step count for secondary prevention of AMI, we will establish a baseline step count for each participant (weeks X-X) and then recommend a X percentage point increase in daily step goal each week during the X-week ramp-up phase (weeks X-X) with a maximum goal of 10,000 steps. After the ramp-up phase, participants will be asked to maintain that daily step goal for the maintenance period (weeks X-X). After X weeks, financial incentives will be stopped and the participants will be followed for an additional X weeks with the same step goal as the maintenance period (weeks X-X) (Include any baseline and follow up periods). Participants will be given daily feedback on whether or not they achieved their daily step goal on the prior day, for the entire intervention and follow-up period. Participants will be told at the beginning of each week during the ramp-up and maintenance phases that $X has been placed in a virtual account for them. Each day during the week that the participant does not meet their daily step goal, $X will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the X-week baseline period or the X-week follow-up period.

 *5.2 Study duration*

This is an X-week study with rolling enrollment beginning in Month Year.

 *5.3 Target population*

Adults age ≥ 18 years with a history of acute coronary syndrome or history of undergoing coronary catheterization for suspected coronary artery disease.

 *5.4 Accrual*

The study population will be drawn from adults at one of the University of Pennsylvania Health System hospitals or clinics. We will aim to enroll X participants. We estimate that a sample size of at least X participants (X per arm) will provide 80% power to detect a difference of 1000 steps in the change in mean daily step count from baseline to maintenance phase between intervention and control, using a 2-sided α of 0.05, assuming a baseline mean step count of 6000 steps in the control group with a standard deviation of 2000 steps, and accounting for a 15% dropout rate.

 *5.5 Key inclusion criteria (Requirements needed to be eligible participate)*

1) Age ≥18 years; 2) ability to read and provide informed consent to participate in the study; 3) history of a) acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); or b) patients having undergone coronary catheterization for suspected coronary artery disease.

 *5.6 Key exclusion criteria (Anything that would make a participant ineligible)*

Typical exclusion criteria:

* Under 18
* Not able to give consent
* Does not speak English
* Does not meet disease or condition requirements (MI, Diabetes, BMI > 25, etc.)
* Already participating in another similar trial
* Not a Penn Medicine patient
* Does not have smart phone- needed for most apps (Fitbit, Nokia, Misfit, etc.)

Example:

1) Inability to provide informed consent; 2) does not have daily access to a smartphone compatible with the wearable device and not willing to use a device that we can provide them; 3) unable or unwilling to participate in a X-week physical activity program 4) already enrolled in an exercise cardiac rehabilitation program prior to hospital admission; 5) hemodynamic instability or NYHA III-IV heart failure; 6) any other medical conditions that would prohibit participation in an 26-week physical activity program; 7) if admitted and not being discharged to home.

**6. Subject recruitment**

Potentially eligible participants will be identified from data requests to Penn Data Store and EPIC, and from the cardiology services or clinics at one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person or by phone. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study. (Include any enrollment steps that the participant will complete through Way to Health either on their own or via a research coordinator in-person or over the phone)

Potential enrollment steps

* Profile to collect contact information
* Informed Consent
* Survey administration- screening, baseline demographic, study specific surveys
* Device authorization and set up
* W9, if paying participants

**7. Subject compensation**

All participants will receive $X for enrolling and $X for completing the X-week study. Participants that choose to attend the optional in-person visit for the six-minute walk test will receive $X for each visit.

Participants randomized to Arm 2 (financial incentive program) will be told at the beginning of each week during the ramp-up and maintenance phases that $X has been placed in a virtual account. Each day that the participant does not meet their daily step goal, $X will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the X-week baseline period or X-week follow-up period.

**8. Study procedures**

 *8.1 Consent*

Upon recruitment, individuals who are interested in learning more about the study will be directed to the Way to Health web portal. Upon reaching the portal, potential participants will be asked to create an account and will then be informed of the details of the study, including its objectives, duration, requirements, and financial payments. If participants are still interested in participating, the Way to Health portal will take them through an automated online informed consent. The consent document will be divided into sections and potential participants will have to click a button to advance through each section. This is to help ensure that participants read the consent form thoroughly by breaking down the form into manageable blocks of text. Successive screens will explain the voluntary nature of the study, the risks and benefits of participation, alternatives to participation, and that participants can withdraw from the study at any time. On the final consent screen, potential participants who click a clearly delineated button stating that they agree to participate in the study will be considered to have consented to enroll. After consenting, participants will complete an online questionnaire to determine their eligibility. Eligible participants will be randomized to one of the study arms and led through an automated description of the details specific to that arm. Participants will be provided with details regarding how to contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants’ individual Way to Health web portal dashboards throughout the study.

 *8.2 Procedures*

Potentially eligible participants will be identified from data requests to Penn Data Store and EPIC, and from the cardiology services or clinics at one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person or by phone. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study.

All participants will receive a wearable device from the study coordinator and be asked to authorize the device to electronically transmit de-identified data to the study database. Participants in this arm will be told to wear the step tracking device for the next X weeks and get used to the device. They will be provided with the study coordinator’s email and phone number to contact with any questions. Participants will be told that they need to sync their wearable device with their smartphone in order for data to be transmitted to the study team. Participants will receive regular reminders during the baseline period to wear and sync their devices. If the study coordinator notices that a participant is not transmitting data during this X-week baseline period, they will contact the participant to determine the reason and offer assistance on how to use the device. After the X-week baseline period is completed, a baseline step count will be calculated using the second week of step count data and ignoring days on which the individual had less than 1,000 steps. We use the second week of data rather than both weeks in case the individual has more activity during the first week simply because they got a new device. We ignore days on which less than 1,000 steps are recorded because prior research suggests that this is unlikely to be appropriate capture of physical activity (Rowe et al. *Pediatric Exercise Science*. 2004;16:1-12. Kang et al. *Measurement in Physical Education and Exercise Science*. 2004;9(4):233-250.) and including these values may inappropriately downward bias the baseline step level for that individual. If at least X days of data are not available to calculate the baseline step count, then the period will extend until at least X days of data are available.

Once a baseline step level has been determined, participants will be sent a message to log into Way to Health to receive further instructions on their arm design as described previously in section 5.1: design.

**9. Analysis plan**

To compare sample characteristics between arms we will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fisher’s exact tests for categorical variables. In our primary analyses, we will compare the change in mean daily step count from baseline to maintenance period. In secondary analyses, we will compare the change from baseline period to ramp-up and follow-up periods. We will also compare change in sleep patterns and for those that participants change in distance in the six minute walk test. All hypothesis tests will be two-sided using a two-sided alpha of 0.05 as our threshold for statistical significance. We will use Stata and/or SAS to analyze the data. We will use multiple imputation for missing data.

**10. Investigators**

List out the PI, as well as any Co-PI and Co-Is

John Smith, MD, PhD is the Principal Investigator (PI) and is an Assistant Professor of Medicine at the Perelman School of Medicine and The Wharton School at the University of Pennsylvania. He has past experience leading six clinical trials using the Way to Health Platform to deploy interventions using financial and social incentives to promote weight loss and increased physical activity. He currently spends 80% of his effort on research and 20% on clinical and teaching activities.

Jane Brown, MD, MBA (Co-PI) is an Assistant Clinical Professor of Medicine at the Perelman School of Medicine. She is a clinical faculty member in the Consultative Cardiology Program, Echocardiography Laboratory and the Cardiac Stress Testing Laboratory at the Hospital of the University of Pennsylvania. Clinically, she is involved in improving and facilitating physical activity in cardiac patients through the development of the Exercise and Sports Cardiology program at the University of Pennsylvania. She currently spends 90% of her effort in clinical and teaching activities.

Mark Williams, MD (Co-Investigator) is a Fellow in Cardiovascular Medicine in the Department of Medicine at the Hospital of the University of Pennsylvania. He has previously led projects using technology‐based solutions to improve the appropriateness of care delivered in the inpatient and outpatient settings. He currently spends 95% of his effort on clinical and teaching activities.

The Clinical Research Coordinator has experience with administering studies involving behavioral interventions and financial incentives, and also has experience training Research Assistants to follow study protocols.

**11. Human research protection**

*11.1 Data confidentiality*

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

 *11.2 Subject confidentiality*

Research material will be obtained from participant surveys, from the wearable devices, and from the 6-minute walk test. All participants will provide informed consent for access to these materials. The data to be collected include demographic data (e.g., age, sex, self-identified race), outcome data, and daily activity data collected by the wearable device. Research material that is obtained will be used for research purposes only. The same procedure used for the analysis of automated data sources to ensure protection of patient information will be used for the survey data, in that patient identifiers will be used only for linkage purposes or to contact patients. The study identification number, and not other identifying information, will be used on all data collection instruments. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the Way to Health web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. All data for this project will be stored on the secure/firewalled servers of the PMACS 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 University of Pennsylvania system managers. We will use highly secure methods of data encryption for all transactions involving participants’ financial information using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. In addition, risk of loss of confidentiality will be minimized by storing completed paper copies of the surveys and signed informed consent forms in locked file cabinets in locked offices accessible only to trained study staff. Each subject will be assigned a unique identifier without identifying information, and data will be entered into an electronic database using only the unique identifier. Only trained study staff will have access to the code that links the unique identifier to the subject’s identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania.

 *11.3 Subject privacy*

Interested participants will be directed to the Way to Health portal where they will be asked to enter data related to eligibility and their demographic characteristics. Enrollment will include a description of the voluntary nature of participation, the study procedures, risks and potential benefits in detail. The enrollment procedure will provide the opportunity for potential participants to ask questions and review the consent form information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Subjects will be given a copy of the consent document. All efforts will be made by study staff to ensure subject privacy.

 *11.4 Data disclosure*

List any outside vendors or integrations who may have information on study participants. Should also include what information they will have and why.

* Wells Fargo or Clincard
* Device vendors (Fitbit, Nokia, Adheretech, etc.)
* Qualtrics (survey administration)
* Twilio (text messaging and IVR)
* Sendgrid (email)
* Outside partnerships or institutions (insurance companies, employers, universities, etc.)

Example:

The following entities, besides the members of the research team, may receive protected health information (PHI) for this research study: Wells Fargo, the company which processes study-related payments. Patient addresses and account balances will be stored on their secure computers. - Misfit Wearables, the company that designs and manufactures the wearable devices used in the study to track participant physical activity. -Twilio, Inc., the company which processes some study-related messages. Twilio will store patients' phone numbers on their secure computers. -Qualtrics, Inc., the company which processes most study-related surveys. Qualtrics will house de-identified answers to these surveys on their secure servers. -The Office of Human Research Protections at the University of Pennsylvania -Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.

 *11.5 Data safety and monitoring*

At the time of discharge from the hospital, all patients are given anticipatory guidance on when to seek medical attention. In addition, participants will be asked to report to the study team any episodes of chest pain, shortness of breath or other changes during periods of exercise. They will be reminded of this at the end of each week of the study. They can either 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. If the participant happens to also enroll in a standard cardiac rehabilitation program and is told that they should be pursuing a different step count than in the study, they will be asked to report that to the study team and their study count goal may be adjusted.

 *11.6 Risk/benefit*

 *11.6.1 Potential study risks*

For most Way to Health studies, the biggest risk is the potential for breach of confidentially.

Example:

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 home-based rehab program tries to motivate a gradual step count increase 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. Another potential risk of this study is a breach of participant confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file that will only be accessed by the study team in the case of an adverse medical event, participant dropout, or if otherwise deemed necessary by the Principal Investigator. All other identifying information will be discarded after initial contact with the Study Coordinator. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants (If paying participants via the Wells Fargo integration, must collect SSN). Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. We will also collect home addresses to mail incentive payments. This will be done through a University of Pennsylvania approved partnership with Wells Fargo. Accidental disclosure of social security numbers could lead to identity theft. We will use commercial-grade encryption to protect social security information in transit. 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.

 *11.6.2 Potential study benefits*

Through participation in this study, each participant will have the potential to increase their physical activity, which could improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis. If this approach is effective, it could have tremendous benefits for society if adopted on a wide scale to help individuals increase physical activity after discharge from the cardiology service. It is expected that other people will gain knowledge from this study and that participation could help understand how to effectively motivate people to become more physically active. Participants may also receive no benefit from their participation in the study.

 *11.6.3 Risk/benefit assessment*

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 a physical activity study. Participants that increase physical activity may improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis.

Informed Consent using Way to Health- Example #1

**UNIVERSITY OF PENNSYLVANIA**

**COMBINED INFORMED CONSENT and HIPAA AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY**

This is a clinical trial led by Dr. XXXX XXXX at the University of Pennsylvania.  This physician and the study staff are available to answer any questions you may have.

Your participation in this study is voluntary, which means that you can choose whether or not to be in the study. Before you can make your decision, you will need to know the study’s purpose, your role in the study, and possible risks and benefits from participating. The following sections will explain the study in detail. After reviewing this information, you will see an option to select whether or not you would like to participate in the study. If you choose to participate and are enrolled, you may withdraw from the study at any time.

**What is the purpose of this study?**

The purpose of the study is to learn more about ways to promote XXXXX.

**How long is the study?**

This study will take about XX months to complete.

**Am I eligible to participate in the study?**

To participate, you need to be 18 to 70 years old, have a body mass index of 25 or greater, have a smartphone or tablet (e.g. iPhone, iPad, Samsung, Google or Android) that is compatible with the wearable activity tracker used in the study, have no medical condition or other reason you could not complete the XX-month study.

If you are participating in another research study focusing on physical activity, you are not eligible to participate in this study.  You can participate if you a member of a program targeting these areas (e.g. exercise class, weight watchers) but not a research study. You must be willing to wear an activity tracker on your wrist during the day and night for approximately XX months. The device will be provided to you at no cost.

**What will happen if I take part in this research study?**

You will first complete a short questionnaire to determine if you are eligible to participate. If you are eligible to participate, you will be mailed a wearable activity tracker to use for about XX weeks. While you get used to wearing the watch, you will be asked to complete a series of online surveys in order to complete enrollment in the study. You will be randomly assigned to one of several physical activity programs.  You may be randomly assigned to participate by yourself or with other participants.

**How will I receive communications from the study?**

You can select whether you would like to receive communications from the study by email or text message.  Standard text messaging charges may apply. You may be contacted daily with feedback on your performance during the study. Additionally, you will be contacted if there is any other study activity that needs to be completed.  You may change your communication preference at any time during the study.

**Will I be paid for taking part in this study?**

Yes, you can receive a total of up to $XXX during the entire study. You will receive $XX to enroll in the study and another $XX for using the wearable activity tracker through X months and completing study surveys.  Additionally, you will receive another $XX for using the wearable activity tracker through one year and completing additional study surveys.

**What information will I need to provide to receive compensation and how is that information protected?**

To mail your financial payments, we will need to collect your name and address. Since all university payments must be reported to the Internal Revenue Service (IRS), we will also need to collect your social security number (SSN). Your information will be kept in a secured, password-protected file at the University of Pennsylvania.  Your information will be transmitted and stored using very secure systems.  The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential.  All of these personnel will have completed research and confidentiality training.

**Are there any costs to participate in this study?**

There is no cost for you to participate in the study. However, if you choose to receive study communications via text message, standard text message charges may apply.  You may select to have all communications sent by email instead.

**Can I stop participating in the study?**

Yes, this study is voluntary.  You can decide to stop participating at any time.  We won’t delete the information about you that we’ve already collected, but we will stop collecting any new information about you and will stop contacting you.  To stop participating in the study, please contact the study staff either by phone at 111-111-1111 or by email at example@waytohealth.org.

**What side effects or risks can I expect from being in the study?**

This study does NOT involve the use of any medications that could lead to side effects.  If you have any health conditions that prevent you from being in a physical activity program, you should not participate in this study.  During the study, information about you and your activity will be recorded.  There is a risk of breach of confidentiality and privacy.  The research team will take precautions to make sure your privacy is maintained.  We will use commercial-grade encryption to protect your information similar to that which is used to protect electronic health records.  Your personal information will only be used by study team members who have been trained to use secure protocols to maintain the privacy of your data.  Whenever possible, data will be de-identified to protect your privacy.

**Are there benefits to participating in the study?**By participating in this study, you will have the potential to increase physical activity, which could improve your health. If this study finds approaches that are effective, it could have benefits for society.  However, it is possible that you may receive no benefit from participating in this study.

**How is my information protected?**

We will do our best to make sure that the personal information we collect about you is kept private and secure. Your personal information will only be given out if necessary (e.g., if required by law to prevent possible injury to yourself or others).

1. Your information will be kept in a secured, password-protected file at the University of Pennsylvania. Your information will be transmitted and stored using very secure systems. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. All of these personnel will have completed research and confidentiality training.
Your SSN will only be shared with the US government if a W-9 form is submitted for tax
2. purposes and will never be disclosed to any other partnering organizations. Please refer to the information below that explains more specifically how your personal information will be used.
* Wells Fargo Bank (to coordinate your study payments)
* Twilio Cloud Communications (to send you text messages)
* Qualtrics (to collect your answers to survey questions)
* Quest (to collect your laboratory blood test measures)
* Nokia (to collect data on your physical activity, sleep patterns, and weight)
* The Office of Human Research Protections at the University of Pennsylvania
* Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.

Once your personal information is disclosed to others outside the University of Pennsylvania, it may no longer be covered by federal privacy protection regulations. You can review the privacy policies of these companies here:

* Wells Fargo: https://www.wellsfargo.com/privacy\_security/privacy/individuals
* Twilio Cloud Communications: http://www.twilio.com/legal/privacy
* Qualtrics: http://www.qualtrics.com/privacy-statement/
* Nokia: http://www.nokia.com/en\_int/privacy

**What other information about me may be collected, used or shared with others?**
To create your account, we will collect your name, date of birth, and ask you questions about your background such as gender, education, and income level.  To contact you during the study, we will collect your email address and phone number.

**Who may use and share information about me?**
Your information may be used by authorized members of the UPenn study team.

**Who, outside of the School of Medicine, might receive my information?**
We will share your name and address with KBM Group using a secure data transfer method, in order to obtain statistics on individuals similar to you, based on the zip code in which you live in. If required by law and/or necessary for oversight purposes, your information may be shared with Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies.  Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.  The Principal Investigator or study staff will inform you if there are any additions to the list in this document during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

**How long may the School of Medicine use or disclose my personal health information?**
Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database.  However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

* You have given written authorization
* The University of Pennsylvania’s Institutional Review Board grants permission
* As permitted by law

**Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your information at any time.  You do this by sending written notice to the investigator for the study.  If you withdraw your permission, you will not be able to stay in this study.  Any information collected before your withdraw from the study may be used by the study team for research purposes.

**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study. You will have access to a copy, via your online dashboard, of this web-based Informed Consent and Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By clicking the button stating that you want to participate in the study, you will be considered to have consented to enroll. This means you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

**Who can I contact with other questions about the study?**
You can contact the study team either by phone at 111-111-1111 or by email at example@waytohealt.org  If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any questions, concerns, or complaints at the University of Pennsylvania by calling 111-111-1111.

**CONSENT**

This consent form will be saved to your online dashboard. From there, you can access and print copies of this consent form whenever you like.

Please select your choice and then click the NEXT button on the right to continue.

* I want to participate
* I do not want to participate

Informed Consent using Way to Health- Example #2

**UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT & HIPAA AUTHORIZATION FORM**

Protocol Title:  A Randomized Controlled Trial of XYZ

Principal Investigator:  John Smith, MD, PhD

Contact: University of Pennsylvania

123 Penn Way

Philadelphia, PA 19104

Phone: 215-123-4567

smith@example.com

Emergency: In the event of an emergency, please contact your primary care physician or go to the nearest emergency room.

**Why am I being asked to volunteer?**

The University of Pennsylvania is partnering with XXXX.  Your participation in this study is voluntary, which means you can choose whether or not you want to participate. In order to assist you in making an informed decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will be asked to do in this study. The following screens will explain the study in detail. After reviewing this information, you will have the option to participate in the study or to not participate. If you choose to participate in this study, you may withdraw at any time.

**What is the purpose of this research study?**

The purpose of the study is to learn more about XXXX. We will test different strategies for helping people XXXX.

**How long will I be in the study?**

How many people will be in the study? The study will last for 24 months. A total of XX adults will participate in the study. The participants will be employees at XXXX.

**What am I being asked to do?**

1. During the enrollment process, you will be asked to complete an online questionnaire. You do not have to answer any questions that make you feel uncomfortable. The online survey should take about 10 minutes to complete.

2. If you meet the necessary requirements for the study, you will be "randomized" into one of 4 research study groups. Randomization means that you are put into a group by chance. A computer program will place you in one of the research groups. Neither you nor the researchers can choose the group you will be randomly placed in.

**What are the possible risks or discomforts?**

The risks of participation are expected to be minimal. All study participants will be screened through eligibility requirements for any health conditions that might worsen by participating in an XXXX study. You may not be in this study if you are pregnant or if you become pregnant during the study. There is a minor risk of loss of confidentiality and privacy. The research team will take the necessary precautions to make sure your privacy is maintained.

**What if new information becomes available about the study?**

During the course of this study, we may find out information that could be important to you. We will notify you as soon as possible if such information becomes available. You will always have the right to change your mind about being in this study. What are the possible benefits of the study? Participation in this study may help you XXXX. There may be many benefits of XXXX; it may result in improvements in high blood pressure, diabetes, high cholesterol, arthritis, sleep apnea, and many other obesity-associated conditions. In addition, the knowledge we gain from the study will assist in helping others.

**What other choices do I have if I do not participate?**

Your alternative to being in the study is to not be in the study. If you choose not to be in the study, you may always consult with your primary care doctor.

**Will I be paid for being in this study?**

Everyone in this study will have the opportunity to earn a total of $XXXX.  In addition, some participants may earn additional money.

In order to be paid for participating in this study, you will be asked to provide your Social Security number. The University of Pennsylvania requires that we collect Social Security numbers for all research participants who get paid for being in a research study. You do not have to provide your Social Security number, but if you choose not to, you will not get paid for your participation.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual is $600 or more in any one calendar year, the University of Pennsylvania is required to report this information to the Internal Revenue Service (IRS). Research participant payments of $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

**Will I have to pay for anything?**

If you choose to receive communication messages from the Way to Health study website in the form of a text message, you will be responsible for the costs associated with the receipt of these text messages. For example, if you have a monthly text-messaging plan, these messages will count towards your monthly text-messaging total. If you do not have a plan, you will be charged the standard text messaging fees by your wireless provider. You may receive a maximum of 35 text messages from the Way to Health study website each month. You can edit your Way to Health profile or contact the study research team at any point during the study to change your communication preferences.

**When is the study over? Can I leave the Study before it ends?**

The study will last for XXXX months/years following the date you enroll. If you decide to participate, you are free to leave the study at anytime. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care. If you no longer wish to be in the research study, please contact the Project Manager.

Your participation in the study may be terminated without your consent for the following reasons:

* The Principal Investigator (PI) feels it is best for your safety and/or health. If this is the reason for termination you will be informed of the reasons why.
* You have not followed the study instructions.
* The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

**Use of Study Materials**

Information about you that is collected during the study will not be given to others (unless it is required by a government agency or other legal authority). This means that no one (not your family, your doctor, your insurance company, or your employer) will have access to this information during the study.

Who can see or use my information? How will my personal information be protected? The Principal Investigators and research staff involved with the study will keep your personal information strictly confidential. It will be kept in a secured, password-protected file at the University of Pennsylvania. At any time, you may ask to see your personal information (such as name and address) and correct it if necessary.

What information about me may be collected or shared with others?

* If you decide to participate we will collect the following information:
* Name, mailing address, electronic mail address, telephone number, and social security number Height, weight, glucose, cholesterol, blood pressure
* Personal characteristics such as age, gender, race, income, education, health
* Questionnaire data about dietary and exercise habits
* Cardiovascular risk factors, including: diabetes, high cholesterol, smoking status, high blood pressure (if applicable)
* Medical benefit claims information from your insurer, which is relevant to our research. (This statement applies only to enrolled participants who are insured by XXXX.
* Biometric screening results from your employer, or your employer’s health management vendor. Information on the use of wellness program activities provided by your employer (if applicable to you).

This information will be collected from the time you enroll in the study, until your completion date of the study.

* The medical benefit claims information, use of wellness program activities, and biometric screening results will only be collected from the time you enroll in the study until your completion date of the study.

This personal information will not be shared with your healthcare providers, your insurance company, or your employer. When you sign this consent form, you agree to have your personal and medical information obtained used as described here.

**Who, outside of the University of Pennsylvania, might receive my information?**

* Wells Fargo (We will share your Name and Address with Wells Fargo in order to coordinate your payments). You can review the privacy policy here: https://www.wellsfargo.com/privacy\_security/privacy/individuals
* Withings (to record your weight from the wireless scale. Withings may also ask you to provide your name and date of birth to create an account in order to set up the scale, if you receive one, but we will not be collecting this information). You can access privacy information on Withings website: http://www.withings.com/en/wirelessscale/faq:
* Twilio Cloud Communication (We will only provide your phone number to send you text messages, and you will only receive study related text messages). You can review the privacy policy here: http://www.twillio.com/legal/privacy
* Qualtrics (We won’t be sharing any of your information with Qualtrics.  We will only be interacting with Qualtrics to use their online survey service and to collect your answers to survey questions)

**Why is my information being collected, and how will it be used?**

* Your personal information will be used by the research team to contact you during the study.
* Your responses to questionnaires and results of weigh-ins will be used to:
	+ Do the research
	+ Oversee the research
	+ Make sure the research was done correctly
* Ensure that payment for your participation in the research is sent to you

**How long may the University of Pennsylvania use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire. Your information will be held in the research database. However, the University of Pennsylvania may not re-use or disclose information collected in this study for a purpose other than this study unless: You have given written authorization to The University of Pennsylvania Institutional Review Board grants permission As permitted by law

**Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study PI (contact information on the first page). If you withdraw your permission, you will not be able to stay in this study.

**What if I decide not to give permission to obtain and use my personal health information?**

Then you will not be able to be in this research study. You will be given a copy of this Informed Consent and Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document you are permitting the University of Pennsylvania to use and disclose personal health information collected about you for research purposes as described above.

**Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the PI listed on Page 1 of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania with any questions, concerns or complaints by calling (215) 123-4567.

**Next steps**

When you click the "I want to participate" button below, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Clicking the "I want to participate" button also means that you are permitting the University of Pennsylvania to obtain and use personal health information collected about you for research purposes within our institution.

Please select your choice and then click the NEXT button on the right to continue.

* I want to participate
* I do not want to participate