UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT & HIPAA AUTHORIZATION FORM

Protocol Title: A Randomized Controlled Trial of Incentives vs Environmental Strategies for Weight Loss
Protocol # 821428

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Principal Investigator (PI): Kevin Volpp, MD, PhD

Contact:
University of Pennsylvania
1120 Blockley Hall
423 Guardian Drive
Philadelphia, PA 19104-6021
Phone: 215-573-0270
volpp70@mail.med.upenn.edu

Project Manager: Karen Hoffer

Contact:
1129 Blockley Hall
423 Guardian Drive
Philadelphia, PA 19104
Phone: 215-746-8437
Email: khoffer@mail.med.upenn.edu

Study Team: The Study Team consists of:

- The Principal Investigator: responsible for the oversight of the Study;
- The Project Manager and Clinical Research Coordinators: responsible for managing the recruitment and enrollment of Study participants and management of all Study procedures listed in this document;
- The Study's data analyst team: responsible for analyzing all Study data
- The Data and Safety Monitoring Board: a selected group, consisting of three faculty members at the University of Pennsylvania, who are responsible for monitoring participants' safety during the Study.

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 three Philadelphia employers: Independence Blue Cross, Southeastern Pennsylvania Transportation Authority (SEPTA), and the City of Philadelphia on a two-year research study to test different ways to help people lose weight and

maintain weight loss. You are being invited to participate in the above-referenced research protocol (the "Study") because you are an employee of Independence Blue Cross, SEPTA, or the City of Philadelphia. 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 sections 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.

Please read this carefully before you agree to participate in this Study.

What is the purpose of this research study?
The purpose of the Study is to learn more about effective ways to lose weight and maintain weight loss. We will test different strategies for helping people lose weight and maintain weight loss.

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 328 adults will participate in the Study. Since enrollment is limited, signing up for the Study does not ensure your acceptance into the Study. The participants will be employees at Independence Blue Cross, SEPTA, and the City of Philadelphia.

What am I being asked to do?
1. During the enrollment process, you will be asked to complete an online questionnaire regarding your age, height, weight, gender and health. You do not have to answer any questions that you do not wish to answer. The online questionnaire 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. Randomized 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.

3. If you meet the requirements for the Study, you will also be asked to complete a survey about your health history, and your dietary and exercise habits. You can choose to not answer any questions that make you feel uncomfortable. We will ask you to complete this survey again at months 6, 12, 18, and 24.

4. The Study will consist of three phases. Phase I of the Study (first 6 months) will focus on weight loss, and you will be encouraged to lose 0.5 lbs. per week. Phase II of the Study (months 7-18) will focus on continued weight loss, or weight maintenance for those who choose it. You will be able to choose a weight loss goal of either 0 or 0.5 lbs. of weight loss per week. Phase III of the Study (months 19-24) will consist of a follow up survey and a final weight measurement.

5. Some participants in the Study will receive a free wireless scale to obtain daily weight measurements.

6. You will have a personalized web portal that you will log into that will allow you to track your weight loss goals and your progress towards meeting your weight loss goals.

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 a weight loss study.

There are medical risks to excessive or very rapid weight loss. Losing more than 10 pounds per week may be harmful to your health. Risks of rapid weight loss include: gallstones (signs of gallstones can include pain in your upper right abdomen, nausea and vomiting, fever, or changes in the color of your urine or stool), constipation, diarrhea, hair loss, feeling too cold. Study staff will monitor your weight and notify the study physician if you have lost an unsafe amount of weight. If you have lost an unsafe amount of weight, the Study physician, who is a member of the Study Team, may contact you and ask you to talk to your primary care physician. In addition, it is possible that if you do not meet your weight loss goals you may experience some disappointment.

You may not be in this Study if you are pregnant or if you become pregnant during the Study. This is because weight loss is generally not recommended during pregnancy.

There is a minor risk of loss of confidentiality and privacy. The Study Team will take the necessary precautions to make sure your privacy is maintained.

Please call the Project Manager, Karen Hoffer, to discuss any concerns you may have about your participation in the Study. Contact information is listed on the first page.

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 lose weight. There may be many benefits of weight loss; weight loss may result in improvements with 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 who are overweight or who attempt weight loss by one of the methods studied.

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 regarding appropriate weight loss and maintenance strategies.

Will I be paid for being in this Study?
Everyone in this Study will have the opportunity to earn a total of $250 for completing weigh-ins at baseline, 6, 12, 18, and 24-month time points. Participants will receive $50 for each weigh-in at the designated time points. In addition, some participants may earn additional money if they successfully lose weight during the Study, up until the 18-month time point of participation.

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 the Study Team collect Social Security numbers for all research participants who get paid for being in a research study. The University of Pennsylvania will use Social Security numbers solely for the purpose of making payments to Study participants. 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). Some research participants may receive payments of $600 or more during any calendar year for participation in the Study. 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.We will not use or disclose your Social Security number for any purpose other than to send you and the IRS notice of any payments to you as required by law.

Will I have to pay for anything?
The Study Team may communicate with you by text message to send you reminders to complete Study requirements at certain time points throughout the Study. If you choose to receive communication messages from the Weigh 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 Weigh to Health study website each month. You can edit your Weigh to Health profile or contact the Study Team at any point during the study to change your communication preferences.

What happens if I am injured as a result of being in the Study?
There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form. If you think you have been injured as a result of taking part in this research study, contact Karen Hoffer (Project Manager of this Study) as soon as possible at 215-746-8437. If you have a medical problem related to the Study, you should immediately contact your own physician in addition to notifying the Study Team.

When is the Study over? Can I leave the Study before it ends?
The Study will last for two years (24 months) following the date you enroll. If you decide to participate, you are free to leave the Study at any time. 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. Should you decide to leave the Study, you will receive all earned compensation payments which you have earned for your participation in the Study.

If you no longer wish to be in the Study, please contact the Project Manager, Karen Hoffer, by phone at 215-746-8437, or by email at khoffer@mail.med.upenn.edu.

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.

Who can see or use my information? How will my personal information be protected?
The Principal Investigator and the Study Team involved with this Study will keep your personal information strictly confidential and will use the information only for conducting this Study and for no other purpose. It will be kept in a secured, password-protected file at the University of Pennsylvania that is accessible only to the Study Team. At any time, you may ask to see any of your personal information that is collected and will be given access to the information you request to see.

Information about you that is collected during the Study will not be given to others (except to the extent the University of Pennsylvania is required by a court order or a state or federal law to disclose the information to a government agency). This means that no one (not your family, your doctor, your insurance company, or your employer) will have access to this information during or after the Study.

If you provide any information concerning intent to harm self or others or any information regarding child abuse, the information will be reported to authorities as required by law.

Authorization for use of Protected Health Information:

This section of the informed consent and HIPAA authorization form identifies three sources of protected health information (referred to collectedly as "Your Personal Information") we may collect and use as part of the Study. By signing this document, you authorize the Study Team to collect and use Your Personal Information for the Study and authorize the other sources of the information to disclose Your Personal Information to the Study Team.

1. <u>Information collected by the Study Team at the University of Pennsylvania</u>

If you participate in the Study, we will collect the following information from you:

- Your name, mailing address, electronic mail address, telephone number, date of birth, height and weight measurement, and your social security number;
- Your age, gender, race, income, education, and health status;
- Data about your dietary and exercise habits which will be provided by you in your responses to an on-line survey; and
- Your cardiovascular risk factors, including: diabetes, high cholesterol, smoking status, high blood pressure (if applicable).
- For individuals in some arms, who decide to join a voluntary Facebook group
    - Facebook e-mail address

By signing this document, you authorize the Study Team to use your Personal Information for the Study as described above. Should you provide any information concerning an intent to harm yourself or others, the Study Team will have a Study clinician follow up with you to further investigate.

2. Information collected from Independence Blue Cross (if you are insured by them)

If you are insured by Independence Blue Cross and participate in the Study, we will collect the following medical benefit claims information about you from Independence Blue Cross :

- The number of your outpatient visits, emergency room visits, and hospitalizations during the period commencing 12 months before you start your participation in the Study and ending on the date your participation in the Study ends;
- the costs of your care relating to these visits and hospitalizations.

We intend to receive the final data file for all enrolled participants at the conclusion of the Study.

We will not seek any information on drug or alcohol counseling, HIV-related services, or mental health. (This statement applies only to enrolled participants who are insured by Independence Blue Cross.)

By signing this document, you authorize Independence Blue Cross to disclose your medical claims information described above to the Study Team for use in the Study as described above. This authorization to permit Independence Blue Cross to disclose your personal information to the Study Team will expire upon the earliest of (1) the completion of the Study; (2) twenty-four months after the date on which you sign this Authorization; (3) the date on which you notify Independence Blue Cross that you have withdrawn (or taken back) your Authorization; or (4) the date on which the Study Team notifies Independence Blue Cross that you have withdrawn from the Study.

3. Information collected from Active Health Management, the City of Philadelphia's wellness vendor

If you participate in wellness program activities offered by the City of Philadelphia, we will collect the following information for the period commencing 12 months before you start your participation in the Study and ending on the date your participation in the Study ends: (a) biometric information (including your height, weight, glucose, cholesterol, and blood pressure) reported by you to the City of Philadelphia's health management vendor, Active Health Management; and (b) how often you used wellness program activities. We intend to receive the final data file for all enrolled participants at the conclusion of the Study.

By signing this document, you authorize Active Health Management to disclose to the Study Team for use in the Study as described above your personal information described in the previous paragraph. This Authorization to permit Active Health Management to disclose your personal information to the Study Team will expire upon the earliest of (1) the completion of the Study; (2) twenty-four months after the date on which you sign this Authorization, (3) the date on which you notify Active Health Management that you have withdrawn (or taken back) your Authorization; or (4) the date on which the Study Team notifies Active Health Management that you have withdrawn from the Study.

Your Personal Information will not be disclosed to your healthcare providers, your insurance company, or your employer.

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

- Wells Fargo Bank: The University of Pennsylvania will disclose your name and address to Wells Fargo Bank to be used by Wells Fargo Bank only as necessary to issue a check to you for your participation in the Study. The University of Pennsylvania will ensure that Wells Fargo Bank does not use or disclose your name and address for any other purpose and will destroy any record of your name and address when you have been fully paid for your participation in the Study." You can review the privacy policy here: *https://www.wellsfargo.com/privacy_security/privacy/individuals*

- Withings (to record your weight from a wireless scale). You may receive a scale as part of your participation in the Study. If you receive the scale, we will ask you to download the application on a smartphone, which is where your weight data will be collected. We will then ask you to create an account on the Withings website. The Study Team will access your daily weight measurements from the Withings website and store your weight data on the Study website . You will be asked to give some identifying information on the Withings website to create an account (e.g. full name, email address, date of birth, and gender). The Withings website also asks for various other health information such as height, weight and age. The Study Team will not share any of Your Personal Information with Withings. Withings will not have access to any of your answers to the survey questions or any other information about you. The Withings website has its own detailed privacy policy available at: http://www.withings.com/en/api.

- Twilio Cloud Communication: We will provide your phone number to Twilio Cloud Communications, a telecommunications service provider through which the Study Team will transmit Study-related text messages to you. You can review Twilio Cloud Communications privacy policy at: http://www.twillio.com/legal/privacy.

- Qualtrics: The Study Team will use tools and services provided by Qualtrics to conduct and collect your answers to the online questionnaires and surveys described above. Qualtrics will not have access to any of your answers to the survey questions or any other information about you.

Why is my information being collected and how will it be used?
Your name, mailing address, electronic mail address, telephone number, and date of birth will be used by the Study Team to contact you during the Study. Your responses to questionnaires, surveys, results of weigh-ins, medical claims data, biometric data, and utilization of wellness program activities data will be used to:

- Conduct the Study;
- Oversee the Study;
- Make sure the Study was done correctly;
- Ensure that payment for your participation in the Study is sent to you; and
- Conduct analysis of the data to determine the results of the Study.

The University of Pennsylvania will not use or disclose Your Personal Information collected or received for this Study for any other purpose.

How long may the Study Team use Your Personal Information?
Your authorization to permit the Study Team to use Your Personal Information for this Study expires forty-two months from the conclusion of your participation in this Study, or when you withdraw from the Study, whichever occurs first. The University of Pennsylvania will securely remove your Personal Information from its databases no later than forty-two months after the Study ends, subject to the following exception: The University of Pennsylvania may retain Your Personal Information for longer than forty-two months after the Study ends to the extent it is required by law to do so.

How long may Independence Blue Cross and Active Health Management disclose my personal information to the Study Team? Your authorization for Independence Blue Cross and Active Health Management to disclose your personal information to the Study Team expires at the end of the Study, twenty-four months after you sign this Authorization, when you withdraw (or take back) your authorization, or when you withdraw from the Study, whichever occurs first.

Can I change my mind about giving permission for use or disclosure of my information?
Yes. You may withdraw or take away your permission to allow the Study Team to use Your Personal Information at any time by sending written notice to the Study Principal Investigator (PI) (contact information on the first page) or by withdrawing from the Study. You may withdraw your permission to allow Independence Blue Cross and/or Active Health Management to disclose Your Personal Information to the Study Team by withdrawing from the Study or by sending written notice to Active Health Management and/or Independence Blue Cross as described below. If you withdraw your permission to allow the Study Team, Independence Blue Cross, and/or Active Health Management to use or disclose your Personal Information for the Study, you will not be able to stay in the Study.

If you withdraw your permission to allow the Study Team to use Your Personal Information, the Study Team will immediately notify Active Health Management and Independence Blue Cross in writing that you have withdrawn from the Study and direct them to stop sending your Personal Information to the Study Team. We will send to you at your last known address a copy of the written notice we send to Active Health Management and Independence Blue Cross.

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 Study.

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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 Study or if you have any other questions, you may contact a member of the Study Team listed on Page 1 of this form. If a member of the Study 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) 898-2614.

At any time during or after the Study, you may contact your departmental Human Resources Representative of the Employee Benefits Unit of the City of Philadelphia's Department of Human Resources, if you should have questions or concerns.

The Employee Benefits Unit of the City's Department of Human Resources, as sponsor of the City of Philadelphia's Group Employee Health Plan, may receive de-identified data reports regarding the health of covered employees. At no time will Active Health Management or Independence Blue Cross notify the Employee Benefits Unit of your participation (or refusal to participate) in the Study.

Can I change my mind about giving authorization to Active Health Management or Independence Blue Cross for disclosure of my information?
Yes. You may withdraw or take away your authorization to permit Active Health Management or Independence Blue Cross to disclose your personal information for the Study at any time. You do this by sending written notice to the Privacy Officer of Active Health Management or Independence Blue Cross, as applicable, whose contact information is below. If you withdraw your Authorization, Active Health Management and/or Independence Blue Cross, as applicable, will not disclose any further information about you to the Study Team for the Study and you will not be able to stay in the Study.

Your withdrawal of your authorization will not affect any actions Active Health Management or Independence Blue Cross takes in reliance on this authorization before they receive your written withdrawal.

The contact information for Active Health Management's Privacy Officer is:

Wahida Bhuyan, Esq.
Senior Compliance Lead
1333 Broadway, New York, NY 10018
Email: WBhuyan@activehealth.net
Tel: 212-981-8308

The contact information for Independence Blue Cross' Privacy Officer is:

Efram Silberstein
Vice President
Audit, Compliance & Privacy Officer
Internal Audit Division
1901 Market Street, 42nd Floor
Philadelphia, PA 19103
(215) 241-2501

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 informed consent and HIPAA Authorization form above, 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 Study Team to obtain and use Your Personal Information collected about you for conducting the Study and that you are authorizing Active Health Management and Independence Blue Cross to disclose your Personal Information to the Study Team as described above.

We encourage you to discuss with your regular doctor your efforts to lose weight and about your participation in this Study.

Your decision not to participate in this Study will not affect in any way your eligibility to receive your health insurance benefits from the City of Philadelphia.

You will be given a copy of this Research Subject Informed Consent and HIPAA Authorization Form describing your confidentiality and privacy rights for this Study

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**