Informed Consent Form

Official title: STEP Together: An Effectiveness-Implementation Study of Social Incentives and Physical Activity

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UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	STEP Together: An Effectiveness-Implementation Study of Social Incentives and Physical Activity
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Research Study Summary for Potential Subjects
You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to test ways to promote physical activity among family members.

If you agree to join the study you will be asked to complete the following research procedures: complete several short surveys at enrollment and at three time points during the study, and wear a Fitbit watch to track your physical activity and sleep patterns for 18 months.

Your participation will last for 18 months.

Benefits to participating in the study include 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. Risks to participating include a risk of breach of confidentiality and privacy as information about you, your

physical activity, and your health will be recorded during the study. More information about how you are protected against this risk can be found in section "What are the risks?" of this consent form. Additional risks include the possibility that answering certain survey questions may cause you to feel slightly uncomfortable. Also, you may experience some skin irritation or a rash from wearing the Fitbit, but this occurrence is rare. More information regarding these risks can be found in section "What are the risks?" of this consent form.

Your alternative to being in the study is to not to be in the study. There is no penalty if you choose not to join the research study.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?
You are being asked to take part in a research study led by Drs. Karen Glanz and Ryan Greysen at the University of Pennsylvania. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. After reviewing this information, you will have the 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. You do not have to make a decision now; you can share the information in this document with your friends or family.

If you do not understand the information or have any questions, please ask the research staff to explain. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study.

What is the purpose of this study?
The purpose of the study is to test ways to promote physical activity among family members.

Why was I asked to participate in the study?
You are being asked to join this study because you:

- Are at least 14 years or older
- Are a member of a team with family or close friends living in the Philadelphia area including at least one adult age 60 years or older.

To participate you must also:

- Have a smartphone (e.g., iPhone, iPad, Samsung, or Android) that is compatible with the Fitbit watch used in the study.
- Have no medical condition or other reason you could not complete the 18-month study.
- Be willing to wear the Fitbit watch on your wrist during the day and night for 18 months. This device will be provided to you at no cost.

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 are a member of a program targeting these areas (e.g., exercise class, Weight Watchers) but not a research study focused on physical activity.

How long will I be in the study?
The study will take place over a period of 18 months.

What will I be asked to do?
1. During the enrollment process, you will be asked to complete several short surveys on the study website about your health, social support, physical activity, sleep, and mood. These online surveys will take between 45 and 75 minutes to complete.
2. You will enroll as a member of a 2-10 person family team. If you are the team captain, you will be asked to provide the name and contact information of other members of your family who wish to enroll in the study. If you are not the team captain, you will be asked to confirm the name of your team captain.
3. If you are eligible to continue, you will be mailed a Fitbit watch to use for several weeks. Then, you will be randomly assigned (placed into a group by chance, like the flip of a coin) to one of three physical activity programs and be asked to use the wearable device for the next 18 months to track your activity levels.
4. You will be asked to complete several short surveys on the study website 6, 12, and 18 months after you begin the study.
5. You may be asked to participate in a telephone interview at the end of the 18-month study.

What are the risks?
This study does NOT involve the use of any drugs that could lead to medication 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, your physical activity, and health 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. 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.

Risks and side effects related to this study include the possibility that answering certain questions in the surveys may make you feel slightly uncomfortable. Also, you may experience some skin irritation or a rash from wearing the Fitbit, but this occurrence is rare.

Study staff will be available to discuss any concerns you may have about your participation in the study. If for any reason you are not comfortable discussing your concerns with study staff directly, the staff can help you find appropriate contact information for someone else you can talk to about these concerns.

How will I benefit from 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.

What other choices do I have?
You may choose not to participate in the study. There is no penalty if you choose not to join the research study.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all the information has been collected for all participants. You will be in the study for about 18 months. The study may be stopped without your consent for the following reasons:

- The Principal Investigators feel it is best for your safety and/or health—you will be informed of the reasons why
- You have not followed the study instructions
- The Principal Investigators, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. We will not delete the information about you that we have already collected, but we will stop collecting any new information about you and will stop contacting you. 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 study staff either by phone at 215-746-1403 or by email at STEP-Together@pennmedicine.upenn.edu.

How will my personal information be protected during the study?
We will do our best to make sure that the personal information we collect about you is kept private and secure. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. 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 investigators 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 Social Security Number will only be shared with the US government if a W-9 form is submitted for tax purposes and will never be disclosed to any other partnering organizations. Please refer to information below that explains more specifically how your personal information will be used with partnering organizations.

• Greenphire ClinCard (to coordinate your study payments)
• Twilio Cloud Communications (to send you text messages)
• Fitbit (to collect data on your physical activity and sleep patterns)
• 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.

You can review the privacy policies of these companies here:
• Greenphire ClinCard: https://greenphire.com/privacy-policy/
• Twilio Cloud Communications: http://www.twilio.com/legal/privacy
• Fitbit: https://www.fitbit.com/legal/privacy-policy

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 Investigators 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.

What information about me may be collected, used or shared with others?
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. Since your physical activity will be monitored by a wearable device, we will keep account of the serial number of your device. Your information will be labeled with a unique code number, and will not include your name or other information that directly identifies you. This information will be combined with information from other people in the study and analyzed after the study is complete.

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- conduct the research
- oversee the research
- to see if the research was done appropriately
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigators of the study, Drs. Karen Glanz and Ryan Greysen, and the study team

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

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 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 School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

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 investigators for the study. If you withdraw your permission, you will not be able to stay in this study. Any information collected before you withdraw from the study may be used by the study team for research purposes.

Will I be paid for taking part in this study?
Yes, you can receive a total of up to $250 during the entire study. This includes $50 to complete enrollment into the study, $30 for participating through 6 months and completing surveys, $70 for participating through 12 months and completing surveys, and $100 for participating through 18 months and completing the surveys. You will be sent a ClinCard, which is similar to a debit card, and your payments will be uploaded to the card after you complete each survey.

In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?
There is no cost for you to participate in the study. However, you will receive study communications via text message and standard text message charges may apply.

Who can I call with questions, complaints, or if I'm concerned about my rights as a research subject?
You can contact the study team ether by phone at 215-746-1403 or by email at STEP-Together@pennmedicine.upenn.edu. 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 question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

Do you wish to participate in the STEP Together study?

◯ **I want to participate**

◯ **I do not want to participate**