MyHeartCounts! - Stanford Mobile Cardiovascular Health Study

Study Information and Consent to Research

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Michael V. McConnell, 300 Pasteur Drive, Suite H2157, Stanford, CA 94305, (650) 723-7476

DESCRIPTION: You are invited to participate in a pilot study on the use of a mobile phone application ("MyHeartCounts! app") to collect research data on your daily activity, fitness, and cardiovascular health status. Prior research using surveys on physical activity and fitness have shown that these can reduce the risk of developing heart and blood vessel disease, such as heart attack and stroke (also called cardiovascular disease). Mobile phones and wearable devices can now measure physical activity and fitness, offering improved methods to research the impact of activity and fitness on cardiovascular health. The goal of this study is to use the quantitative capabilities and wide availability of mobile devices to enhance our knowledge of the relationships among activity, fitness, and heart health. You will be asked to download the MyHeartCounts! app on your smartphone and go through screens that will determine eligibility, describe the study to you, and ask you to provide informed consent. If you provide consent, a copy of this consent form will be emailed to you. You will then be asked to allow the MyHeartCounts! app to collect health and activity data from your phone, followed by survey questions about any history of cardiovascular disease and risk factors. At the beginning of the study and for up to 3 months, the MyHeartCounts! app will ask you to do 3 things: 1) use your phone, or any wearable activity device you have, to collect activity data for 7 days; 2) perform a 6-minute walk evaluation, which uses the phone (or wearable) to measure the distance you can walk in 6 minutes; and 3) provide survey information about risk factors and heart disease status. The surveys should take you 15-20 minutes at the beginning of the study, and 10-15 min to update at the end of the study. The MyHeartCounts! app will provide feedback on all 3 items above: your 7-day activity level, your 6-minute walk distance, and your American Heart Association cardiovascular risk evaluation. The MyHeartCounts! app will also provide educational links to learn more about any of your data. At times during the study, the app may provide additional information about your heart risk, additional methods to follow your activity level, or the ability to share your data with family or friends (with your permission). For this pilot study, research staff may contact you to provide feedback about good or bad features of the app in order to improve it for future users.

RISKS AND BENEFITS: There are no significant risks associated with this study. The study will make every effort to protect your privacy and the privacy of your data. For this exploratory pilot study, your data will not be stored permanently nor included in the overall study. Benefits that may reasonably be

expected to result from this study are that you will be given the opportunity to use a mobile health application and learn more about your activity, fitness, and heart risk. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment or medical care.

TIME INVOLVEMENT/COSTS: Your participation in this pilot study will last up to 3 months. If you participate in this study, there may be additional costs to you. These include the personal time it will take to respond to the survey questions, perform the study tasks, and provide feedback about the app to the research staff. Participation in this study is not a substitute for health care or health insurance. You and/or your health insurance must pay for any services, supplies, procedures, and care that you require during this study for routine medical care.

PAYMENTS: You will not receive any payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed. You have the right to refuse to answer particular questions.

CONTACT INFORMATION:

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Michael V. McConnell, 650-723-7476. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;

- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Name of Adult Participant	Signature of Adult Participant	Date