

## STANFORD UNIVERSITY Research Consent Form

*IRB Use Only*

Approval Date: March 3, 2015

Expiration Date: November 30, 2015

Protocol Director: Michael V. McConnell, M.D.

Protocol Title: MyHeart Counts - Stanford Mobile Cardiovascular Health Study

**FOR QUESTIONS ABOUT THE STUDY, CONTACT:** Dr. Michael V. McConnell, 300 Pasteur Drive, Suite H2157, Stanford, CA 94305, myheartcounts@med.stanford.edu, (650) 721-3944

**DESCRIPTION:** You are invited to participate in a research study on the use of a mobile phone application ("MyHeart Counts 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 MyHeart Counts 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 MyHeart Counts app to collect health and activity data from your phone, followed by questions about your physical activity readiness and any history of cardiovascular disease and risk factors. At the beginning of the study and every 3 months, the MyHeart Counts 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) if able, perform a 6-minute walk evaluation, which uses the phone (or wearable) to measure the distance you can walk in 6 minutes; and 3) input information about risk factors and any change in heart disease status. The surveys should take you less than 5 minutes each, so active participation should be less than 10-15 minutes per day for the 7 days. The MyHeart Counts app will provide feedback on all 3 items above: your 7-day activity level, your 6-minute walk distance, and your cardiovascular risk evaluation. The MyHeart Counts app will also provide educational links to learn more about any of your data. The MyHeart Counts app will continue to collect activity data in between the 3-month timepoints and you can continue to use the app to view your data. We will NOT access your personal contacts, other applications, personal photos, texts, or email messages. At times during the study, the app may provide additional information about your heart risk, additional methods to encourage you to increase your activity level, or the ability to share your data with family or friends (with your permission). You may also be re-contacted in the future about additional research opportunities, including adding other health data to your MyHeart Counts data.

**RISKS AND BENEFITS:** There are no significant risks associated with this study. You will be asked to complete a survey on your readiness to increase physical activity and test fitness. To prevent improper access, we will use a random code instead of your name for the main study data and this coded study data will be encrypted and stored on a secure cloud server run by Sage Bionetworks, a non-profit research organization. While your coded data in this database will not contain information that is traditionally used to identify you, people may develop ways in the future that could allow someone to link your health information in this database back to you. For example, someone could compare information in this database with information from you in another database and be able to identify you. It

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also is possible that there could be violations to the security of the computer systems used to store the codes linking your health information to you. However, your privacy is very important to us and the study will make every effort to protect your privacy and the privacy of your data, but that cannot be completely guaranteed. Your coded data (without your name) will be combined with data from other participants for analysis by Stanford researchers and its research partners. You also have the option to allow your coded study data (i.e., without your name) to be shared with other qualified researchers who meet criteria established by Stanford. Your choice is indicated at the end of this form. Stanford will maintain your consent and personal information and the link to your study data to enable future research. 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.

The study is currently intended only for use in the US. If you go outside of the US during the study, then you should not use the app while you are outside of the US. If you use the MyHeart Counts app outside of the US, your data will be sent to the US where laws may not protect your privacy to the same extent as in the country from which the data have been sent.

**TIME INVOLVEMENT/COSTS:** There is no cost for the MyHeart Counts app. Your initial participation in this study will last approximately 1 week, though we are hopeful you will continue using the app to monitor your activity. We will ask you to contribute 7-day data every 3 months for at least 1 year. We may also ask you to try methods, such as coaching through the app, to encourage you to increase activity and heart health. 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 and perform the study tasks. The MyHeart Counts app and participation in this study are not a substitute for health care or health insurance. The data collected by the MyHeart Counts app will not be reviewed by a physician for medical evaluation. Consult a physician for any medical questions. 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.

**FUNDING:** The MyHeart Counts study is funded by Stanford Medicine, with software development support from Apple Inc. Your data will not be shared with Apple.

**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.

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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, myheartcounts@med.stanford.edu, 650-721-3944. 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.

Your data sharing preference:

☐ Your data will be shared only with Stanford and its research partners

☐ Your data will be shared with Stanford and other qualified researchers worldwide