Apple Heart & Movement Study FAQs

General Questions

What is the Apple Heart & Movement Study?

The Apple Heart & Movement Study is a research study designed to help advance the understanding of heart health and activity. Your data and participation in this study will help researchers learn how your activity and habits can contribute to a healthier heart and general wellness.

Why is this study being done and why should I participate?

Some health conditions may be prevented simply by staying active. This study will look for factors that affect heart health and potentially cause deterioration in mobility or heart function. Your Apple Watch and iPhone can help researchers gain a better understanding of potential early warning signs. This can lead to new interventions and products that will help millions lead longer, healthier, and more active lives.

How does this study work?

You can participate in this study with your iPhone, Apple Watch, and the Apple Research app. The study will ask you to:

- Provide your consent to collect data from your iPhone and Apple Watch, such as your Health app data, medical history data, sensor data, and other device/Apple Research app related data.
- Complete occasional surveys about your fitness, mental health, and day-to-day habits.
- Wear your Apple Watch daily and use the Workout app when you exercise.

Who is the sponsor of this study?

Apple.

Who is the principal investigator of this study?

Dr. Calum MacRae from Brigham and Women's Hospital is the principal investigator of this study. Brigham and Women's Hospital, a major Harvard Medical School affiliate, is a global leader in cardiovascular health research and has pioneered breakthroughs that have improved lives around the world.

Who are the research collaborators of this study?

Apple is collaborating with the American Heart Association and Brigham and Women's Hospital to conduct this research. For nearly 100 years, the American Heart Association has been a relentless force for a world of longer, healthier lives, dedicated to ensuring equitable health in all communities.

How long will this study last?

This study is expected to last at least five years. We will ask you to renew your consent to continue in the study every two years. You can withdraw from the study at any time.

What is the last day I can join this study?

You are welcome to join this study any time, as long as you meet the participation requirements.

Will I be able to see the results of this study?

As study findings are published (for example, in a scientific journal), they will be posted on ClinicalTrials.gov. Note that your name and other directly identifying information will not be used in any study results.

Is this study different from the Apple Heart Study?

Yes – the Apple Heart & Movement Study and Apple Heart Study are different studies. The Apple Heart Study was an innovative research study conducted to accelerate discovery in heart science and to evaluate if Apple Watch could help with early diagnosis of irregular heart rhythms such as Atrial Fibrillation. Apple Heart Study completed enrolling over 400,000 participants in 2018.

Participation Requirements

Who can participate in this study?

Anyone who meets all of the participation requirements may participate:

- You own an Apple Watch Series 1 or later paired with your iPhone
- You are at least 18 years old (at least 19 years old in Alabama and Nebraska; at least 21 years old in Puerto Rico)
- You live in the United States of America
- You are comfortable communicating in written and spoken English
- You have installed the Apple Research app on your iPhone
- You do not share your iCloud account, iPhone, or Apple Watch with anyone else
- You are willing and able to provide informed consent to participate in the study

Is this study available in languages other than English?

The study is currently only available in English.

Can I use a friend or family member's iPhone to participate?

No, you can only use your own iPhone with your own iCloud account. This is to ensure data integrity.

Do I need an Apple Watch to enroll and participate in this study?

Yes, an Apple Watch is required to enroll and participate in the study.

Can I use an Apple Watch from a friend or family member for this study?

Yes, as long as it is paired with your own iPhone and you are the only person using the Apple Watch for the duration of the study.

Can I enroll if I am already participating in another research study?

Yes.

Procedures

How do I enroll in this study?

You will need to download the <u>Apple Research app</u> from the App Store and install it on your iPhone and Apple Watch. In the Research app, you'll find the studies you can enroll in. You will need to select the Apple Heart & Movement Study and go through the introduction and consent process.

What will I be expected to do if I participate?

You will be asked to provide your permission to collect your heart rate, activity, and other health data. You will control exactly what data you share. You will also be asked to wear your Apple Watch, log your workouts using the Workout app on your Apple Watch, and complete occasional surveys in Research app about your fitness, mental health, and day-to-day habits. If you experience an event like falling or receiving an irregular heart rhythm notification, you may be asked to complete additional survey questions.

What should I do when I am physically active?

Please use the Workout app on your Apple Watch to log a workout when you are physically active. This will help the study get accurate measurements of your movement.

What happens if I fall? What is Fall Detection on Apple Watch?

If the apps and sensors on Apple Watch Series 4 and later detect a fall or potential fall, you may receive an additional survey to learn more about your fall so that we can improve the fall detection feature on Apple Watch. Apple Watch cannot detect all falls and you may not receive a survey each time you fall. This feature is not automatically turned on as part of this study. Visit the support page to learn more about Fall Detection on Apple Watch.

How does the Apple Watch measure my heart rate?

Apple Watch can calculate the number of times the heart beats each minute – your heart rate. Visit the <u>support page</u> to learn more about how Apple Watch measures your heart rate.

What is an irregular rhythm notification?

Your Apple Watch will occasionally look at your heart beat to check for an irregular heart rhythm that might be atrial fibrillation (AFib). This feature is not automatically turned on

as part of this study. Visit the <u>support page</u> to learn more about notifications from the Heart Rate app on your Apple Watch.

What is the ECG app?

The ECG app on Apple Watch Series 4 and later can record an ECG. An electrocardiogram (also called an ECG or EKG) is a test that records the timing and strength of the electrical signals that make the heart beat. By looking at an ECG, a doctor can gain insights about your heart rhythm and look for irregularities. This feature is not automatically turned on as part of this study. Visit the support page to learn more about ECG app on Apple Watch.

What happens if I have health issues while participating in the study?

Participation in this study is not a substitute for medical care or medical advice you get from your doctor or other health care provider. You should continue to see your regular doctor and keep any scheduled physical exams, cardiac screening procedures, and medical appointments. Always seek professional medical advice whenever you need it.

Do I have to sign an informed consent form?

You do not have to sign an informed consent form, but if you do not sign, you will not be able to participate in the study. The informed consent form will be available for you to read and sign in the Apple Research app. If you choose to join the study, a copy of your signed informed consent form will be made available to you in the Apple Research app as well.

What happens if I change my mind about being in this study?

You can stop participating in the study at any time by opening the Apple Research app, tapping on the Studies tab, and then selecting the Apple Heart & Movement Study. "Withdraw from this study" appears at the bottom. If you withdraw, we will not delete study data that we have already collected about you, but we will stop collecting any new information about you and will turn off further notifications. If you delete the Apple Research app, you will not be withdrawn from the study.

Participation

Will participation in this study cost me anything?

There is no direct cost to you for participating in the study. There may be an indirect cost because the data collected as part of the study and transmitted to the study team will count against your phone's data plan. Additionally, standard phone usage and text messaging rates may apply if you communicate with study staff via phone or text message. This study does not provide medical care, and the sponsor is not financially responsible for any treatment you seek from your own health care provider.

Do I get compensated for my time involved in this study?

No, you will not be compensated for taking part in this study.

What is the commercial gain associated with this study?

Study data may be used for health-related product development and improvement. The sponsor has no plans to offer you financial compensation or share any profits from the commercialization of any products, technologies, processes, or services developed using the study data. You will not, however, lose any legal rights to which you are entitled by agreeing to participate in this study.

Privacy

What data will be collected?

With your permission, the study may collect or access data such as your demographic information, Health app information, sensor and usage data from your iPhone and Apple Watch (if applicable), and survey responses. You control what data you share and can stop sharing data with the study at any time.

Please refer to "What data will be collected?" in the informed consent form for more information on the specific data types that may be collected.

How will my data be protected?

Any information collected or accessed by the Research app is stored with encryption if you have a passcode on your iPhone. Information from the Research app will be shared with the study only after you have joined the study by signing the informed consent form, and authorized the study to collect or access information in the Research app. Your information will be encrypted when transferred to and stored on Apple's servers.

Who will have access to my data?

Only certain authorized people and institutions will have access to the study data. These include Apple, Brigham and Women's Hospital, the American Heart Association, and the Research Studies Support Center. Advarra Institutional Review Board and certain regulatory or government agencies may also have access to the study data.

Most will only have access to Research app data with directly identifying information (such as your name, email address, and phone number) removed. However, if required for study-related purposes, Research app data that include directly identifying information will be accessed by the principal investigators at Brigham and Women's Hospital, and may be accessed by the Research Studies Support Center, Advarra Institutional Review Board, and certain regulatory or government agencies.

Please refer to "Who will have access to my study data?" in the informed consent form for more information about who has access to the study data and what types of study data they may access.

Will Apple have access to any information that directly identifies me or know that I'm participating in a study?

Apple will not be able to access any information that directly identifies you (such as your name, email address, and phone number) that is collected through the Research app.

However, if you call the Research Studies Support Center regarding a technical issue with the Research app, the Research Studies Support Center may ask you if you want to be transferred to AppleCare for additional support. With your consent, you may be transferred to help address your technical question(s), in which case Apple may have access to certain information that directly identifies you and may know that you are participating in a study.

Apple Research App

What is the Apple Research app?

The Apple Research app can be used to find available Apple research studies, understand the goals of the study, see the data it will collect, and enroll and participate in the studies by providing consent.

How do I install the Apple Research app?

You can install the <u>Apple Research app</u> by searching for it in the App Store on your iPhone. Apple Research app requires an iPhone 6s or later with iOS 13.2 or later.

How can I control the notifications from the Apple Research app?

Notifications from the Apple Research app can be controlled in your iPhone by going to: Settings > Notifications.

What happens if I upgrade or downgrade my iPhone?

Please ensure that you backup your iPhone information, and then restore from backup in order to prevent loss of any information. Visit the <u>support page</u> to learn more about how to backup your iPhone information.

If you do not backup your iPhone information, and wish to continue to participate in the study, you will need to complete the onboarding and consent process for the study again. If you have iCloud Keychain enabled, your participant identifier may be preserved, allowing researchers to link your previously collected data with the new data after you re-join.

What happens if I delete the Apple Research app?

If you delete the Apple Research app, it will disable notifications and end all study data collection. Please note that deleting the Apple Research app will not withdraw you from the study.

If you re-install the Apple Research app after deleting it and wish to continue participating in the study, you may complete the onboarding and consent process for

the study again. If you have <u>iCloud Keychain</u> enabled, your participant identifier may be preserved, allowing researchers to link your previously collected data with the new data after you re-join.

Contact Information

Who can answer my questions about this study?

If you have questions about the study that are not covered by the FAQs or you think you have an injury or illness as a result of the study, please call the Research Studies Support Center at 833-237-3881 (a toll-free number staffed 24/7).

The Research Studies Support Center is hosted by Apple's third-party service provider and is staffed by employees of the service provider who are trained to handle study issues and certain technical issues related to the Research app. Please do not reach out to Apple directly with any questions about the study.

If you experience a technical issue related to the Research app, the Research Studies Support Center may ask you if you want to be transferred to AppleCare for additional support.

Who should I contact for medical emergencies?

For medical emergencies, please call 911 or local emergency services.

If you have study questions that you wish to discuss with a physician from the study team, and it is NOT a medical emergency, please call 857-348-9946.

What is an IRB? How can I contact it?

An institutional review board (IRB) is an independent research ethics committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail: Study Subject Adviser, Advarra IRB, 6940 Columbia Gateway Drive, Suite 110, Columbia, MD 21046
- or call toll free: 877-992-4724 (M-F between 8:00 am to 6:00 pm ET)
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser at Advarra IRB: Pro00036784.

Link to study website. http://www.bwhresearch.org/appleheartandmovementstudy/

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