COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Longitudinal evaluation of patterns associated with wearable device use in the community (the PRECARDIA cohort)

Principal Investigator (the person who is responsible for this research):
Rohan Khera, MD, MS
195 Church Street, 6th Floor
New Haven, CT 06510
Telephone Number: 203-764-5885
Email Address: rohan.khera@yale.edu

Research Study Summary:

• You are being invited to participate in a research study.
• This study seeks to evaluate patterns of use of wearable devices that could be used in the future to monitor health in the community. You are invited to participate because you are an active user of an eligible smartwatch or wearable device.
• As part of this study, you agree to share your wearable and health record data with a secure research platform created by Yale University Investigators.
• Your data will be coded along with information extracted from your electronic health record to better understand the potential value of wearables in cardiovascular health.
• There will be no other interventions and the app will not send you notifications. • This study poses minimal risks to participants. Risks related to loss of confidentiality will be minimized by study procedures.
• The results of this study could benefit broader public health initiatives, as new wearable technologies may enable a reliable screening tool for cardiovascular disease.
• Participation in this study is entirely voluntary. You can decide to join or not join the study or change your mind at any point without any impact on your regular medical care or legal rights.
• We encourage you to contact the study team to learn more about the study or if you have any questions or concerns after you read this consent form.

Why is this study being offered to me?

We are exploring the patterns of wearable device use in our communities. Wearables, such as smartwatches, are increasingly used by individuals to monitor their activity and overall health. We seek to enroll 10,000 individuals who use smartwatches to understand the patterns of wearable use, such as what devices people use, how often, how consistently and describe the type and quality of information obtained, including activity levels, step counts, electrocardiographic signals etc. You are invited to participate since you are an active user of one of the two eligible devices (Apple Watch or Fitbit).

Who is paying for the study?

There is no dedicated funding for this study. The study is currently funded by internal funds of the study's Principal Investigator.

Who is the Principal Investigator of the Study?

The Principal Investigator of the study is Dr. Rohan Khera, a general cardiologist at Yale. He is the Director of the Cardiovascular Data Science Lab at Yale, where the CarDSPlus application was developed exclusively for academic research purposes. Dr. Rohan Khera, the principal investigator for this study, is named as an inventor on a patent application on the use of electrocardiographic signals obtained on wearable devices, but the technology has not been licensed to any commercial or non-commercial entity.

What is the study about?

This research seeks to describe patterns of wearable use in our community and understand the type and quality of health information that wearable devices may acquire. Furthermore, the study explores whether objective health-related information collected by commercially available wearable devices are associated with objective cardiovascular health metrics in the health records. If you are interested, you can choose on your smartphone what information you are willing to share from your wearable device. By doing this, you will consent for the research team to access your existing and new wearable data from Apple or Fitbit in a non-identifiable way. By signing this informed consent form you consent for the research team to access your electronic health record data. All data will be processed in an anonymized fashion, using a non-identifiable study ID. You will not receive any notifications or any results, beyond any information that you

already receive through your existing device. You will not be required to attend any in-person visits and we will not send any data to your medical providers. You will only be contacted by email at the end of the study or if you at any time decide to stop participating, to acknowledge the end of data sharing.

What are you asking me to do and how long will it take?

Please read this document carefully. If you have questions or concerns about participating in the study, we encourage you to reach out to our research team at cards@yale.edu or at 203-764-5885. Monday through Friday 9 am through 5 pm. If you agree to participate, you will be asked to confirm your consent by signing at the end of this page. You will then be brought to a second page to enter your information, including first and last name, date of birth, sex, and your medical record number (if known). Any personal and identifiable information will be stored securely in a server approved for research use that will only be accessible by the study investigators. Next, you will receive a non-identifiable participant ID number that will be unique to you and will allow you to link your wearable data to the study by following the instructions on the app. This ID will allow study investigators to link your wearable data and your electronic health records while safeguarding against any unauthorized identification by third parties. The application will enable us to access the information acquired through your wearable device, including retrospective and prospective data on activity levels, step counts, sleep data, heart rhythm, heart rate, accelerometer data, oxygen saturation, blood pressure recordings and ECGs if available, and nothing more than what you choose to share. You will receive no results and no notifications as part of this study. There will be no visits. At the end of the study, the transmission of data from your wearable will be automatically disabled by the research investigators.

What are the risks and discomforts of participating?

We anticipate minimal risks to participants as part of this study. You are invited to participate since you are an active user of a wearable device, and the potential risks associated with wearable device use are no different than the ones listed by the vendors in their manuals. One additional risk is the potential loss of confidential information. However, we will take all required measures to minimize the possibility of losing confidential information. Any data collected as part of this study will be shared using a de-identified study ID, and only the investigators will hold the key to your identifiable information which will be stored on secure servers. This will ensure that third parties cannot identify you from the collected data.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

The study will not benefit you personally. However, it might help individuals in the future by enabling the use of wearables for the timely diagnosis of heart diseases.

How can the study possibly benefit other people?

The benefits to science and other people may include the clinical application of wearable modes in timely detection of cardiovascular diseases which leads to earlier medical treatment and better outcomes.

Are there any costs to participation?

There are no costs to participation. You will use your existing wearable device and the research application is made available for free. There will be no notifications, no test results, and no need for either remote or in-person follow-up visits.

Will I be paid for participation?

There will be no other compensation for participating in the study.

What are my choices if I decide not to take part in this study?

You can choose to not participate in the study. It will not affect your routine clinical care.

How will you keep my data safe and private?

We will keep information we collect about you confidential. Your identifiable information (name, date of birth, medical record number) will be entered into a secure, approved platform to generate a non-identifiable ID number that will be specific to you but will prevent third parties from identifying you. Any data collected as part of the study (e.g., wearable signals) will be stored using these non-identifiable ID numbers to prevent the loss of confidential, identifiable information. Only the study investigators and approved personnel affiliated with Yale University will have access to the secure platform that will contain the key that links your participant ID with

your personal information (i.e., medical record number, name, date of birth, sex). When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for your permission. We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

The research data, along with information from your medical record, may be used to assess the preliminary performance of wearable-based prediction models. However, as discussed, no conditions will be ruled in or out in the present study, and you will not receive any reports from us. Therefore, the absence of any findings or reports does not mean that you are healthy. Your data may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. If such data is shared for future studies, all identifiable information will be removed.

What Information Will You Collect About Me in this Study?

As part of this study, eligible study investigators may access further information through your electronic health record. The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records
- The entire research record and any medical records held by the Yale New Haven Health System created from: 01/01/2015 to study end including laboratory, imaging (radiographic, CT scans, MRI scans, ultrasound) results, medications, diagnostic testing results and other medical diagnoses recorded in the health record. EHR information will be gathered on a monthly basis until the conclusion of the study (5 years after its start, estimated around April 2029).

- Wearable signals (e.g., activity levels, daily step counts, accelerometer data, electrocardiographic signals, blood pressure measurements if available, oxygen saturation measurements as available), including all retrospective data from the wearable device stored in the smartphone. When you download the research application, you will have an option to select which of the above data that are available on your device (step counts, daily activity data, electrocardiographic, oxygen saturation, blood pressure etc) you are willing to share with our research team.

How will you use and share my information?

We will use your information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- We also request that we access the encrypted data that you have already shared and will be sharing with the vendor of your specific wearable device (Apple or Fitbit). We will link this information to you using your unique non-identifiable participant ID. We will not share any protected health information with any of these vendors or external third parties.

We will ensure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I agree to the information in this document?

By agreeing, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may easily withdraw your permission by selecting the relevant option on the CarDSPlus application, which will stop the transfer of any new data from your device to our research platforms. If you have any questions about this process, you can contact our study staff (cards@yale.edu OR 203-764-5885) or by writing to Rohan Khera, MD, MS, 195 Church Street, 6th Floor, New Haven, CT 06510. A study investigator will assist you through this process.

If you withdraw your permission, you will not be able to stay in this study, but the care you get from your doctor outside this study will not change. No new health information (through your wearable or electronic health record) identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can select the relevant option on the research application (CarDSPlus [CarDS+]), or can email or call a member of the research team (cards@yale.edu OR 203-764-5885) at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?

If you stop participating, your data will be fully deidentified. Data collected prior to the time you stop participating would be retained in deidentified form.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can email or call the Study Coordinator (cards@yale.edu OR 203-764-5885).

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at +1(203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

Participant Printed Name	Participant e-Signature	Date