



Name and Clinic Number

Approval Date: January 10, 2024
Not to be used after: January 9, 2025

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Evaluation of Voice and ECG Transmission and AI models Using Voice, ECG and Health Data Collected Using a Mayo Clinic Center for Digital Health (CDH) developed App for a Repository: Mayo Clinic CV Research for Heart & Voice Study

IRB#: 23-012146

Principal Investigator: Paul A. Friedman M.D. and Colleagues

Key Study Information

Table with 2 columns: Question/Section and Answer. Rows include: Introduction (This section provides a brief summary...), It's Your Choice, Research Purpose, and What's Involved.



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Table with 2 columns: Key Information, Learn More. Key Information text: Your voice, ECG recordings and health data will not be reviewed immediately... Learn More text: If you are interested in learning more about this study, read the rest of this form carefully.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. You will receive an electronic copy of this form to keep back from Adobe.



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Contact Information

Table with 2 columns: 'If you have questions about ...' and 'You can contact ...'. Rows include contact info for Principal Investigator (Dr. Paul Friedman), Study Team Contact (Jennifer Dugan), Institution Name and Address (Mayo Clinic), Mayo Clinic Institutional Review Board (IRB), Research Participant Advocate (RPA), and Patient Account Services.



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### Why are you being asked to take part in this research study?

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You are being asked to participate in this research study because you have the Mayo Clinic app.

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### Why is this research study being done?

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The purpose of the study is to determine whether voice and symptoms data from smart phones can be used to monitor health and wellness. The data collected from this study will be used to attain regulatory approvals and product development for detection of cardiovascular and non-cardiovascular health conditions.

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### Information you should know

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#### Who is Funding the Study?

Mayo Clinic is funding this study.

#### Information Regarding Conflict of Interest:

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research, and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.
- Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict-of-Interest Review at (507) 284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.



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How long will you be in this research study?

All voice, symptoms, and ECG data recorded will be securely transferred to Mayo Clinic through the CV Research App. Your study involvement will continue for up to 5 years or longer if you choose. You may stop participation any time.

What will happen to you while you are in this research study?

If you agree to be in the study, you be asked to review and sign this consent document. You will receive a copy of your consent to your email from adobesign@adobesign.com. You may review your research participation and signed consent in a message you will receive after consent in your patient services app. The message will contain a link to the CV Research App. Alternatively, you can simply download the CV Research App from your smartphone at either the Apple store for iOS users or Play Store for Android users.



CV Research
Mayo Clinic

The CV Research App will verify you have signed this consent form. Please sign into app with your patient services username and password. The first time you access the app, it will present a screen on research and a screen on data security. If you are an iOS user, it will ask you for permission to set your preferences on which data captured you would like to transfer to Mayo Clinic investigators from the Health app. A full list of all health data will be presented, and you will be asked to select which items you choose to share with Mayo Clinic. If you own an Apple watch with ECG capability and you choose to share ECG data, please select electrocardiogram (ECG) so the CV Research App may transfer historical and future ECG recordings stored on your smartphone. Android users will skip the step on transferring ECGs, symptoms, activity, clinical and sensor data.

You will then be taken to the My Tasks screen, where you may select Record Voice. The next screen will outline instructions for acquiring the voice recording; please allow the pop-up access to your microphone. Then you will begin by pronouncing vowel sounds, and a short script will follow. The voice recording should take 2 minutes. After submitting the recording, you will see your Task History and can toggle back to My Tasks or sign out until the next day or at the frequency you choose to record voice.



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We ask that at a minimum you record a voice and ECG every 14 days, but daily recordings at your convenience is preferred. Only the data you choose to share will be collected from your phone, and securely transferred to Mayo Clinic study investigators.

The app will enable a Mayo Clinic care provider to review your ECGs in the Cardiology tab of your medical record under AI ECG Dashboard. If you would like to notify your care team that you are in the study and they can review your Apple Watch ECGs, you may do so. Your care team will not know these ECGs data are there unless you tell them. Please note that you must contact your care team if you are concerned about your health. **This study is not a substitute to seeking routine or urgent medical care as you normally would.**

Your medical record may be accessed to compare the voice and health data collected by your personal devices to data in your medical record. Your study data will be used for research and to screen for health and cardiac abnormalities. The data collected from this study will also be used to attain regulatory approvals and product development for detection of cardiovascular and non-cardiovascular health conditions.

After 3 weeks of using the app, a pop-up may be presented to study participants asking if you would be willing to talk to the app developers at Mayo Clinic to provide feedback on your app experience. It is optional and you may indicate whether you choose to provide feedback or not.

**Study investigators will not provide interpretations of the data to you. The app will notify you when a publication is available, or you can get in touch with the study team if you would like more information.**

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### **What are the possible risks or discomforts from being in this research study?**

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Your voice, ECG recordings and health data will not be reviewed immediately. This research does not take the place of your healthcare provider. If you need medical assistance, please call or visit with your health care provider. You will not receive any additional interpretations from the ECGs you record other than the ones you receive from your Apple Watch.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. This is true with all speech research as speech samples have the potential to identify an individual. Additional information about protecting your samples is detailed below.



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Speech database

Your data will be stored on a secure server. Your speech sample will not be part of your medical record. Access to the speech data will be restricted and logged.

Data sharing

To build diagnostic tools, we may have to work with researchers at other academic institutions or for-profit companies. This will require that we share your voice, ECG recordings and health data. We will not share any other identifiable information, such as your name, date of birth, or address. However, even without any other information there is a risk in sharing speech data because someone may be identified based on their ‘voiceprint’. Any sharing will happen through a data-sharing agreement that requires stringent protection of your speech data and prohibits further sharing or disclosure of your data for purposes not related to this study.

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**Are there reasons you might leave this research study early?**

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You may decide to stop the study at any time. To withdraw, you may discontinue use of the CV Research App.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don’t follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used. We will tell you about any new information that may affect your willingness to stay in the research study.

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**What are the possible benefits from being in this research study?**

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There are no direct benefits to you from taking part in this research study. It is for the benefit of research and potentially to detect heart and other health conditions from voice recordings in the future.



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**What alternative do you have if you choose not to participate in this research study?**

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This study is only being done to gather information. You may choose not to take part in this study.

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**What tests or procedures will you need to pay for if you take part in this research study?**

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You won't need to pay for the CV Research App, or anything done just for this research study.

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your usual clinical care, including co-payments and deductibles.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

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**Will you be paid for taking part in this research study?**

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You will not be paid for taking part in this study. You will also not be offered a share of any profits resulting from the use of samples and information.

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**Will your information or samples be used for future research?**

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Your voice, health, clinical and sensor usage data, including Apple Watch ECGs data collected as part of this research will be stored in a secure research database at Mayo Clinic and will be retained forever. This information may be used for future research, regulatory approvals and product development or shared with other researchers including those at for-profit or commercial entities to further scientific developments without your additional informed consent. If data is





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shared outside of Mayo Clinic your identifying information would be removed. If you decide to withdraw your participation, the data collected may still be used, but no new information will be collected.

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### How will your privacy and the confidentiality of your records be protected?

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Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Once the data are downloaded into the CV Research App it will be analyzed only by the research staff with permission to access the information. The data will be collected and stored in a repository at Mayo Clinic for product development and regulatory approvals and used to detect cardiovascular and non-cardiovascular health conditions. Product development may include sharing data with Mayo Clinic collaborators for product testing and validation, as described below.

During this research, information about your health will be collected. Under a federal law called the Health Insurance Portability and Accountability Act (the “Privacy Rule”), health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or “authorization”) to Mayo Clinic.

#### Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including data collected during the use of the CV Research App

#### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

#### Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.



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- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

**How your information may be shared with others:**

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports, or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic, or other methods), or remove your identifying information from Mayo Clinic.

**Is your health information protected after it has been shared with others?**

Mayo Clinic asks anyone who receives your health information from us, for example during an audit to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

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**Your Rights and Permissions**

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Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying ‘no’ will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.



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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic  
Office for Human Research Protection  
ATTN: Notice of Revocation of Authorization  
PL 3-02  
200 1st Street SW  
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: [researchparticipantadvocate@mayo.edu](mailto:researchparticipantadvocate@mayo.edu).

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever unless you cancel it.



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**Enrollment and Permission Signatures**

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**Your signature documents your permission to take part in this research.**

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|              |                   |                    |
|--------------|-------------------|--------------------|
| Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm) |
|--------------|-------------------|--------------------|

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Signature