

Study Title: Phono- and Electrocardiogram Assisted Detection of Valvular Disease

NCT Number: Pending

UCSF CHR Number: 17-21881

Date: 3/1/18

Informed Consent Form

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: Phono- and Electrocardiogram Assisted Detection of Valvular Disease (PEA-Valve Study)

This is a medical research study. Your study doctor(s), John Chorba, MD, or the Study Coordinator, from the UCSF Department of Medicine, Division of Cardiology will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have or will have undergone a clinical echocardiogram here at UCSF.

Why is this study being done?

The purpose of this study is to test whether the data obtained from the Eko Duo and Eko Core Electronic Stethoscope Systems and their heart sound analysis can identify valvular abnormalities found by echocardiography. We want to know whether listening to your heart with this device could be used in place of an echocardiogram for screening certain heart conditions.

This study is being funded by Eko Devices, Inc., which makes the electronic stethoscope system and its analysis algorithm.

The investigators have no financial or proprietary interest in the study.

How many people will take part in this study?

About 900 people will be enrolled at UCSF to take part in this study.

What will happen if I take part in this research study?

If you agree to be in this study, a healthcare provider affiliated with the study will listen to your heart with the electronic stethoscope and record your heart sounds. This will take about ten additional minutes. *There will be no impact to your medical care in the UCSF system.*

After listening to your heart sounds, an electronic copy of the recording will be stored for research purposes. In addition, the results and data from your echocardiogram and additional valvular tests will also be stored for research purposes. The data will be linked using a unique, random identifier, and all personal information will be de-identified to protect your privacy.

The current standard of care is to listen to heart sounds with an analog stethoscope. This device improves upon this standard by recording and analyzing heart sounds. This device itself is

currently FDA approved, but the heart sound analysis is still under development, and therefore no results from the study device will be used to make clinical care decisions.

Before you begin the main part of the study...

You only need to provide your consent. Your medical care will not be affected.

During the main part of the study...

A healthcare provider will listen to your heart sounds with an electronic stethoscope.

When the study is finished...

The provider will record the heart sounds, and your medical care will be unaffected. No information from the electronic stethoscope will enter your medical record.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you would like to stop.

What side effects or risks can I expect from being in the study?

There are no medical risks associated with listening to your heart sounds with either the Eko Duo or Eko Core Electronic Stethoscope Systems.

Are there benefits to taking part in the study?

There is no direct benefit to you from participating in the study. However, this study will help doctors learn more about the Eko Duo Electronic Stethoscope System, and it is hoped that this information will help in the diagnosis and treatment of future patients with suspected heart conditions.

What other choices do I have if I do not take part in this study?

You can choose to have your medical care without the additional heart sound examination.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. If you do not have a UCSF medical record, one will be created for you. Your signed consent form will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The clinical study investigators
- The University of California
- Eko Devices, Inc.
- US Food and Drug Administration (FDA)

What are the costs of taking part in this study?

You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. John Chorba, or the study coordinator, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or page him at 415-443-4363.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor Eko Devices, Inc., depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Dr. John Chorba at 415-443-4363.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will also be asked to sign a separate form authorizing access, use, creation or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

IRB# 17-21881

**University of California San Francisco (UCSF Health)
Permission to Use Personal Health Information for Research**

Study Title (or IRB Approval Number if study title may breach subject's privacy):

Phono- and Electrocardiogram Assisted Detection of Valvular Disease (PEA-Valve Study)

Principal Investigator Name: John Chorba, MD

Sponsor/Funding Agency (if funded): Eko Devices, Inc

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that **UCSF Health** can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by **UCSF Health** it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing **UCSF Health** to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

- | | | |
|---|--|---|
| <input checked="" type="checkbox"/> Entire Medical Record | <input type="checkbox"/> Lab & Pathology Reports | <input type="checkbox"/> Emergency Dept. Records |
| <input type="checkbox"/> Ambulatory Clinic | <input type="checkbox"/> Dental Records | <input type="checkbox"/> Financial records |
| <input type="checkbox"/> Progress Notes | <input type="checkbox"/> Operative Reports | <input type="checkbox"/> Imaging Reports |
| <input type="checkbox"/> Other Test Reports | <input type="checkbox"/> Discharge Summary | <input type="checkbox"/> History & Physical Exams |
| <input type="checkbox"/> Other (describe): | <input type="checkbox"/> Consultation | <input type="checkbox"/> Psychological Tests |
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C. Do I have to give my permission for certain specific uses?

Yes.

The research team will also be collecting information from your medical record that is marked by the check box. The following information will only be released if you give your specific permission by putting your initials on the line(s).

- I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment. _____(initials)
- I agree to the release of HIV/AIDS testing information. _____ (initials)
- I agree to the release of genetic testing information. _____ (initials)
- I agree to the release of information pertaining to mental health diagnosis or treatment. _____ (initials)

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor’s representatives including but not limited to the contract research organization (CRO), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

- There are no optional research activities.
- The research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process. _____(initials)

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

Subject's Name (print)--*required*

Subject's Signature

Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

Parent or Legally Authorized Representative's Name (print)	Relationship to the Subject
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Parent or Legally Authorized Representative's Signature	Date
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Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness' Name (print)

Witness' Signature

Date

Instructions for Researchers: Do not make any changes to this form other than the following items:

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Page 1, Item B: Mark all sources of PHI that will be released
2. Page 2, Item C:
 - a. Check the first box if any of the 4 categories of sensitive information will be collected
 - b. Then, check the box **only** for each specific type of information that will be collected for this study
 - c. Obtain the participant's initials **only for the specific types of information**
3. Page 3, Item G:
 - a. Check one of the boxes indicating if there are optional research activities or not
 - b. Obtain the participant's initial **only if the study involves optional research activity**
4. Page 3, Item J: Obtain the participant's name, signature, and date; *complete subsequent signature lines **if applicable***
5. Provide the subject with a signed copy of the form

Note: The Word document of this form allows you to check the boxes electronically. You can make a 'master version' of this form for this study with all pertinent boxes checked.
