

# A New World of Engagement

## The Health eHeart Initiative

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# Overview

- Health eHeart Study: Engaging research subjects
  - Rationale, goals, design
  - Highlight modular consent and co-enrollment systems
  - Recruitment and data
- Health eHeart Alliance: Engaging citizen-scientists
  - Philosophy and approach
  - Connection with PCORnet
- Engaging YOU
  - Emerging opportunities for novel, efficient research
  - A series of invitations

# Health eHeart Team

- Jeff Olgin Study PI
- Greg Marcus Study PI
- Debbe McCall Alliance Patient PI
- Carol Maguire Study PD
- Madelaine Faulkner Alliance PD
- Geoff Tison Alliance Co-lead



# The Health *e*Heart Study™

Using big data to reduce heart disease


# The Health eHeart Study

- Overarching Goal:
  - Do tech-enabled research that improves cardiovascular health
- Approach:
  - Collect “big data” from all-comers
  - Keep marginal costs low
  - Support ancillary studies, including RCTs

Welcome x


← → ↻ <https://www.health-eheartstudy.org> ☆ 📌 ☰

Apps google - Google Search Search APEX portal MyAccess Box K program PPRN HeH Group: Health eHeart ... Dropbox Dev site Log In » Other bookmarks



 Home Study Technology Team FAQs Login

# Join the study to end heart disease.

Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference. Anyone can join — whether you have heart disease or not.



[Join the Study](#)

Brought to you by  UCSF teaming up with  American Heart Association. Life is why™

### BASIC INFORMATION

Contact Information

Basic Demographics

### ACTIVITY & WELL-BEING

DASI Survey

IPAQ

SA-NYHA

SF12

### HABITS & LIFESTYLE

Detailed Smoking History

Second Hand Smoke

Alcohol Use

Epworth Sleepiness Scale

Pittsburgh Sleep Quality

FFQ

### CONNECTIVITY

Social Demographics

Emergency Contact Information

Internet/Smartphone Use

Internet Use for Medical Information

### MEDICAL HISTORY

Mother Family History

Father Family History

Sibling Family History

General Family History

Medical Conditions

Symptom Overview

Past Cardiovascular Procedures

Medications

TRIGGERED

Coronary Disease Survey

Seattle Angina Survey

Heart Failure Survey

KC Cardiomyopathy Survey

AF Survey

AF Severity Scale Survey

AF Effect on Quality of Life

Chest Pain Symptoms

Shortness of Breath Symptoms

Palpitations Symptoms

Fainting Symptoms

Calgary Syncope Survey



GINGER.io



- **Background continuous data collection from smartphone sensors**
  - Mobility & Activity
  - Screen interaction, call/text interaction
  - Behavior modeling
- **Reminders/Messaging**
- **Contextual alerts**

iHealth™



Pulse Oximetry



BP



Wt/Body Comp

fitbit



# Integrated devices and apps

Withings





# Modular Consent System

- Start with “umbrella” consent to answer surveys and use data for research
- Then offer easy, short, just-in-time consent modules for each optional feature
  - Each device company
  - Medical records/HIPAA Authorization
  - Food Frequency Questionnaire
  - Ginger.io and Azumio apps
  - In-person testing, biobanking


# 2-Step Fitbit Consent Module

**Connect your Fitbit**

It's easy. Clicking the button will take you to their website to enter your Fitbit login and authorize the connection.

Once you do this, we can import the data from you Fitbit devices into your profile, and we'll use it to fight heart disease!

We'll keep your Fitbit data (**private and secure**), just like we do with all your study data.



**Connect** Cancel



**fitbit**

Health eHeart Local by UCSF would like to access your profile and data on Fitbit.com:

🔓 + 🔑 **READ AND UPDATE ACCESS** ⌵


Email

Password

[FORGOT PASSWORD?](#) **ALLOW**

You can revoke this application's access from your Fitbit account settings.

**Not using Fitbit yet?**



- 🏃 TRACK ACTIVITY & SLEEP
- 📊 MANAGE WEIGHT
- 📅 WATCH YOUR PROGRESS

Fitbit motivates you to turn fitness into lifestyle, challenge friends, set goals, and watch your progress. [Learn more about Fitbit](#)

**CREATE A NEW ACCOUNT** ➔

# Modular Consent System

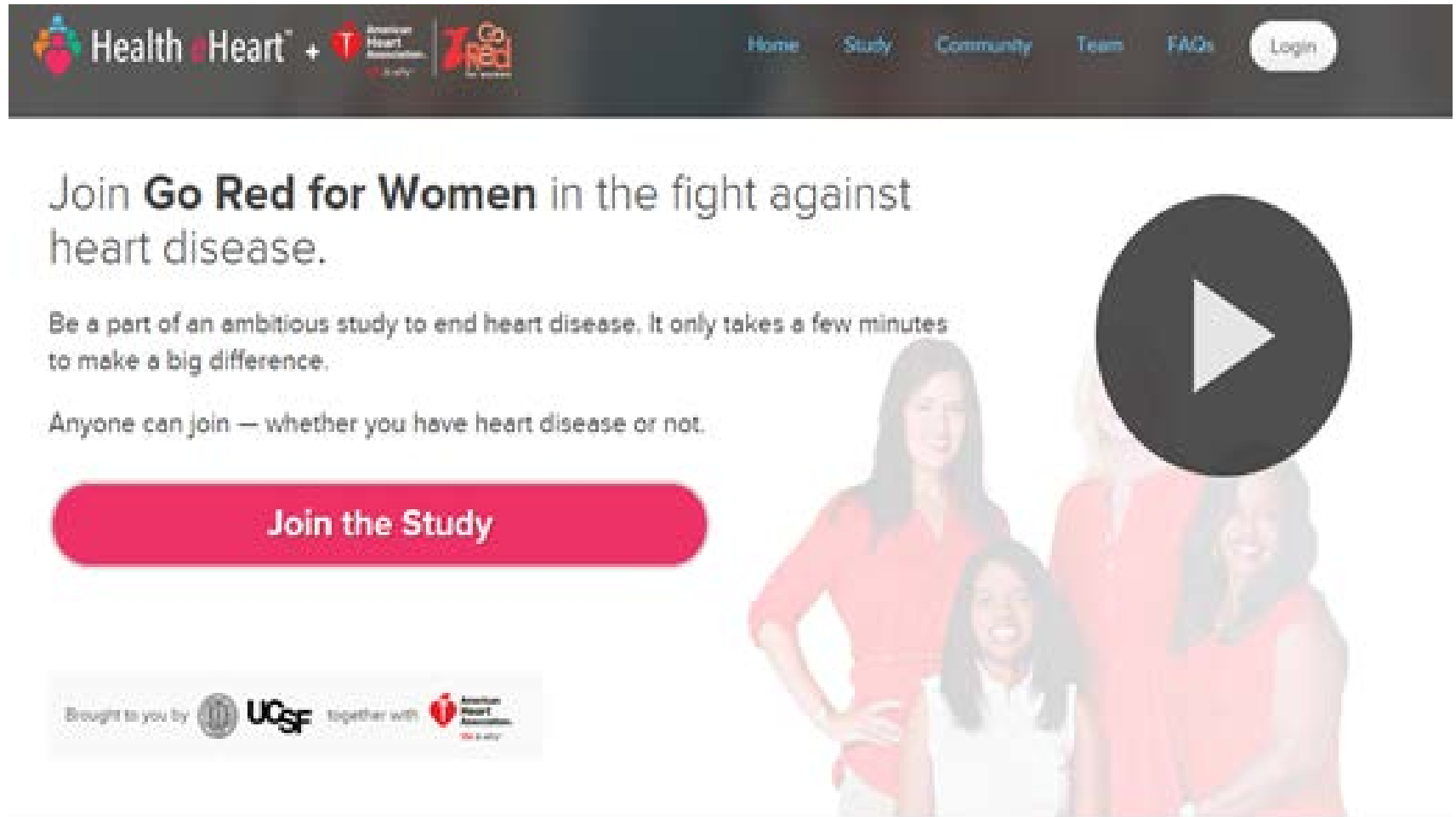
- Tech Detail: We use Oauth 2.0 – an industry standard – for authentication/ “integration”
- Extremely efficient and secure

# Referral and Co-Enrollment Tracking Systems

- Unique URL for each referring partner
  - Customized landing page
  - Track source of recruitment
- Add identifier for “co-enrollment” of individual participants
  - <http://www.health-eheartstudy.org?rfk=4b62fda3607d1425482271&id=ABC123>
  - Link with data assets provided by a referring partner
  - “Mail-merge” is only requirement for partner

# Example #1

<https://www.health-eheartstudy.org/gored>



The image shows a screenshot of a website for the "Go Red for Women" study. The header is dark grey with the "Health eHeart" logo on the left, which includes a heart icon with a pulse line. To the right of the logo are the "American Heart Association" logo and the "Go Red for Women" logo. Further right are navigation links for "Home", "Study", "Community", "Team", and "FAQs", followed by a "Login" button. The main content area has a white background. It features a large heading: "Join **Go Red for Women** in the fight against heart disease." Below this is a sub-heading: "Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference." A third line of text says: "Anyone can join — whether you have heart disease or not." A prominent red button with rounded corners says "Join the Study". On the right side, there is a large, semi-transparent image of four women in red and white clothing, with a large black play button icon overlaid on it. At the bottom left, there is a footer area that says "Brought to you by" followed by the UCsf logo and "together with" followed by the American Heart Association logo.

Health eHeart + American Heart Association | Go Red for Women

Home Study Community Team FAQs Login

Join **Go Red for Women** in the fight against heart disease.

Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference.

Anyone can join — whether you have heart disease or not.

[Join the Study](#)

Brought to you by UCsf together with American Heart Association

# Example #2

<https://www.health-eheartstudy.org/?rfk=69da54e535641439234236&id=A>



[Home](#)

[Study](#)

[Community](#)

[Team](#)

[FAQs](#)

[Login](#)

**UCSF Medical Center**

## Welcome UCSF patients! Join the study to end heart disease.

Be a part of an ambitious study to end heart disease. It only takes a few minutes to make a big difference. Anyone can join — whether you have heart disease or not.



[Join the Study](#)

# Referral and Co-Enrollment Tracking Systems

- Successful campaigns
  - AHA's Go Red for Women
    - 11,000 participants (almost all women!)
  - UCSF patients
    - 200,000 emails → 6,000 ppts (3% uptake)
    - Linkable to medical records if they consent
  - Childhood Cancer Survivors Study
    - 500 → 310 (63% uptake)
    - Linked Fitbit data to CCSS Cohort data

# Referral and Co-Enrollment Tracking Systems

- An invitation for YOU:

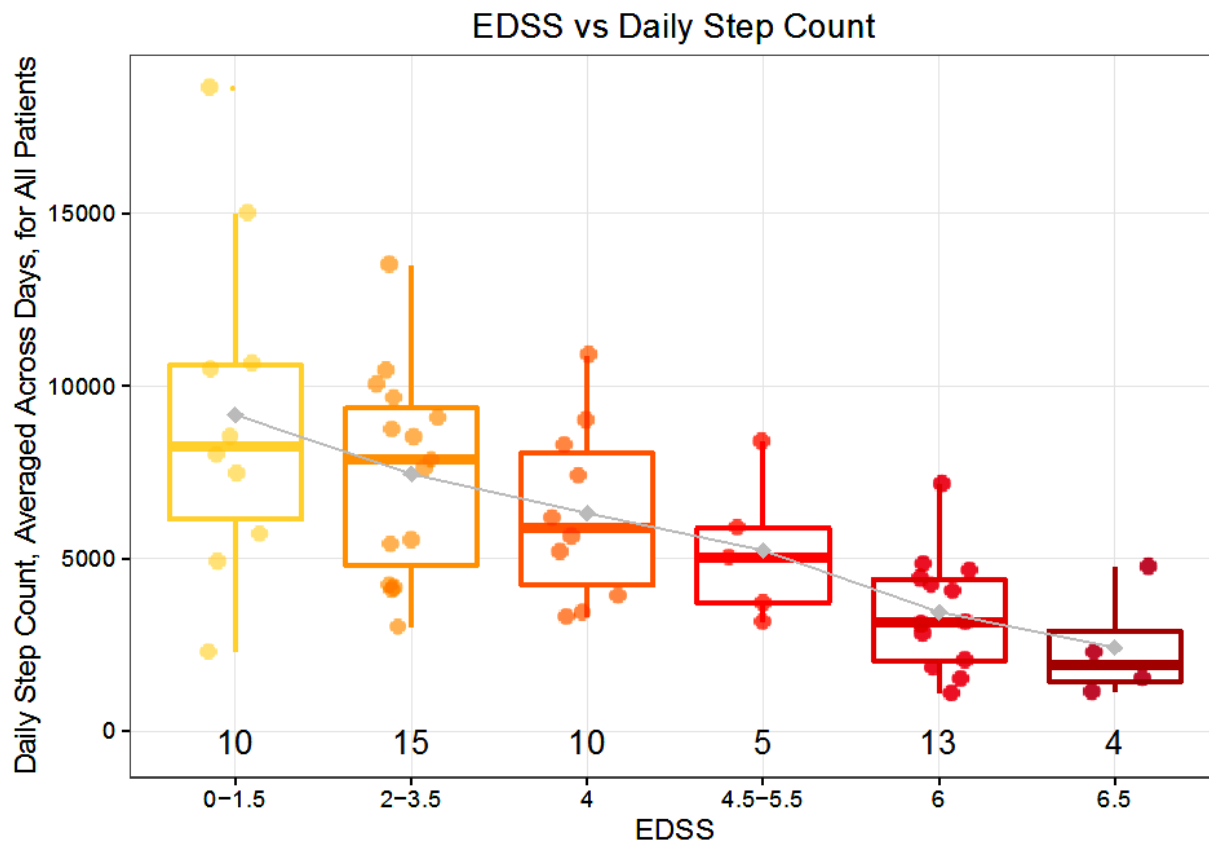
HeH can collect mHealth data for your study

(No study is too small)

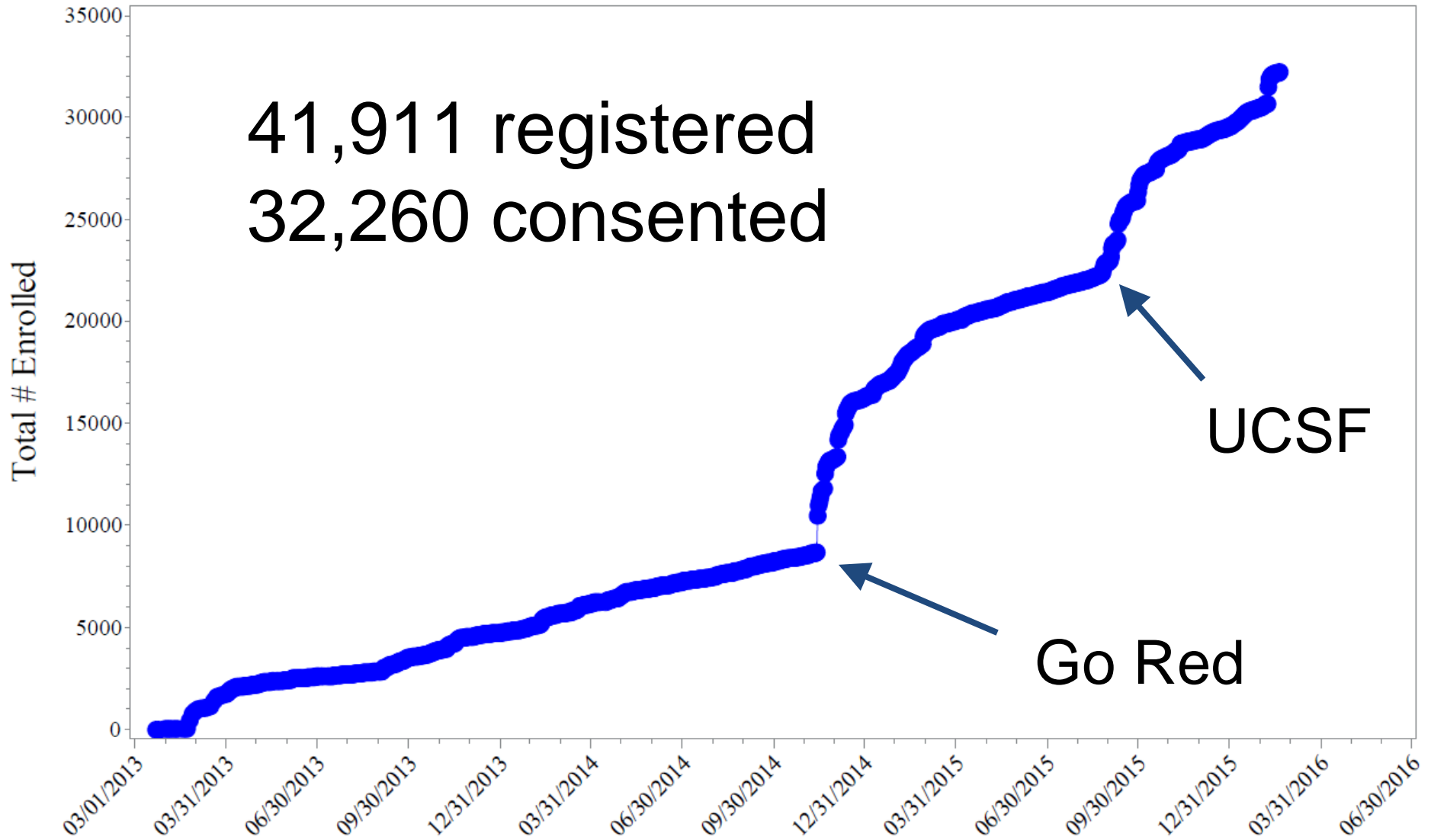


# Small MS study that used HeH

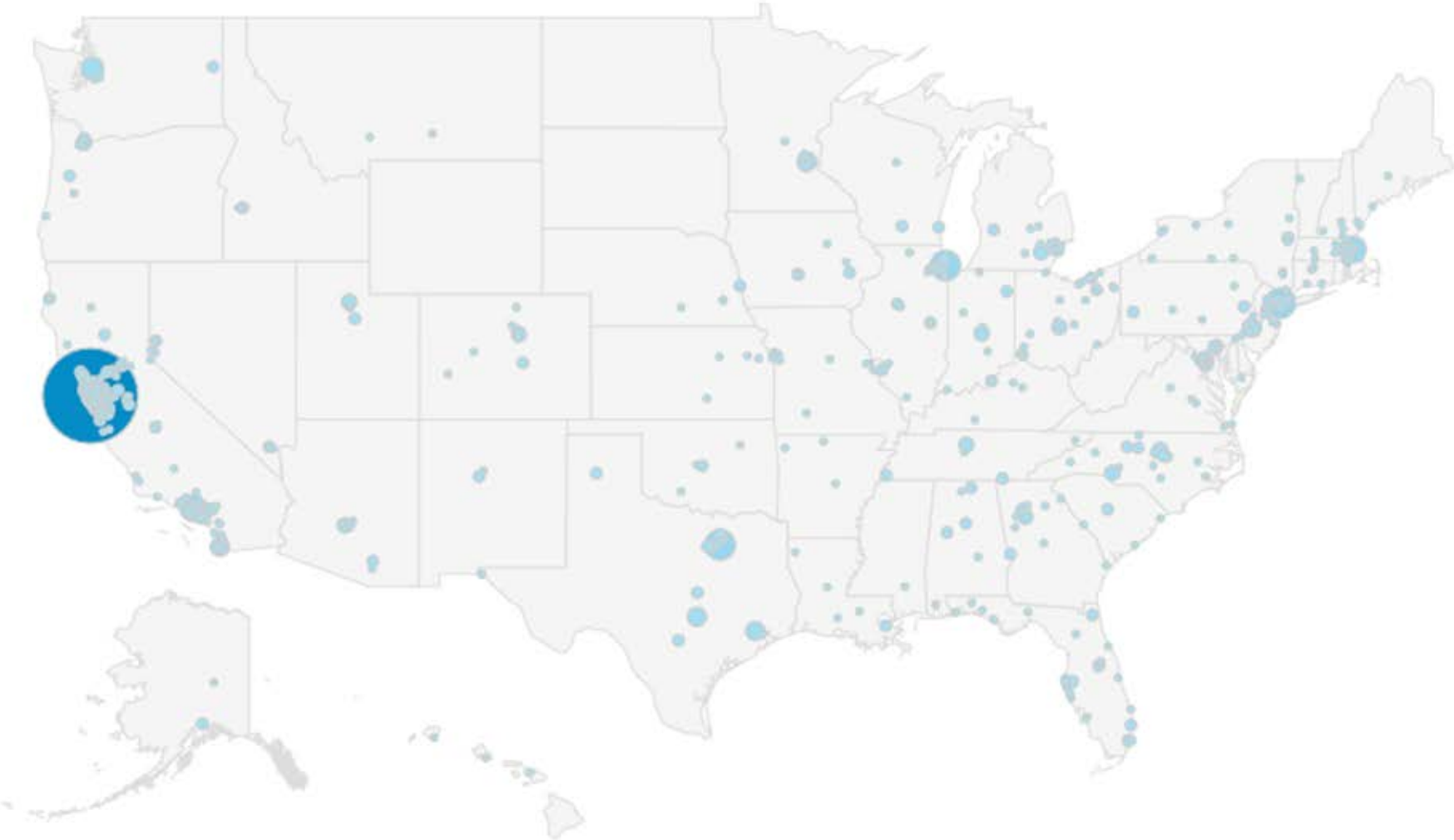
- Fitbit steps: a marker of disability in Multiple Sclerosis



# Recruitment



**United States Geographic Distribution (Cities): Consented Participants via Google Analytics**



# Big Data

## Self report

- **685,424** surveys completed (from n=28,289 people)
- **19,689** blood pressure measurements (from n=10,795)
- **5,585** LDL measurements (from n=7,691)
- **1,876** Food frequency questionnaires (from n=1876)

## Participant-triggered device measurements

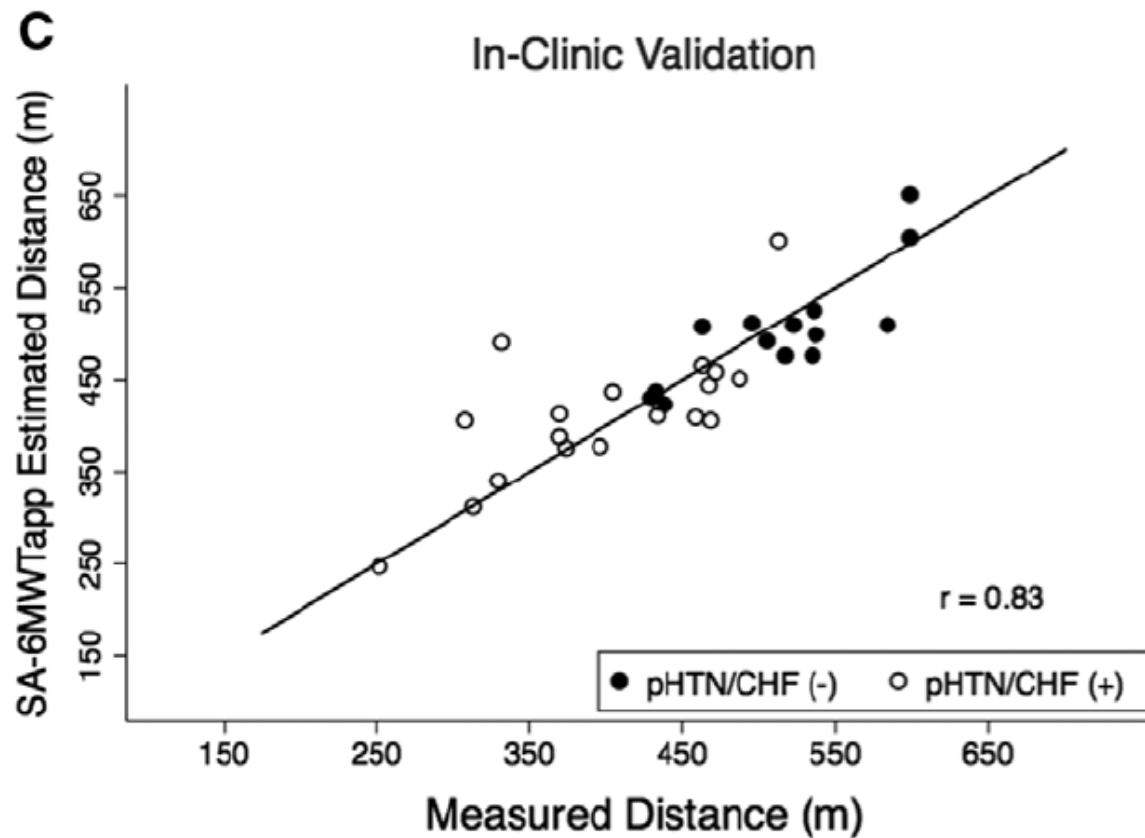
- **246,209** weights (from n=643)
- **35,145** blood pressure measurements (from n=419)
- **45,078** EKGs from AliveCor monitors (from n=406)
  - **1,089** with an Afib flag (from n=76)

## Passively collected device/app measurements

- **821,787** daily step counts (from n=1709)
- **314,418** days of Ginger.io-derived movement/communication patterns (from n=2264)
- **283** hospitalizations detected from **121** hospitals (n=156)

# New measurement: 6MWT by app

- Validation in patients with and without disease



# Summary - Health eHeart Study

- A grand experiment in research engagement
- Success: efficient recruitment and collection of tech-enabled measurements
- Challenge: volunteers are not representative of the population
- Primary value: Platform to support mHealth/tech-related research



The Health *e*Heart *Alliance*

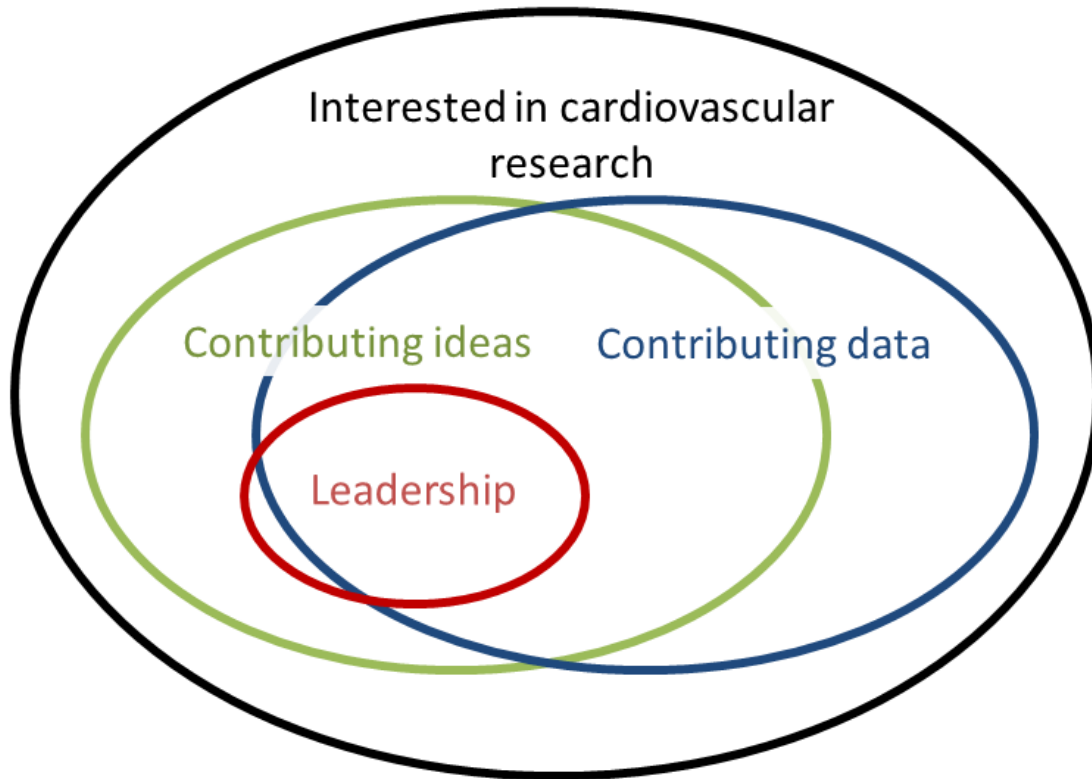
# The Health eHeart Alliance

- A Patient-Powered Research Network
  - Funded by PCORI
  - A member of PCORnet
- Goal: Pioneering new ways to empower patients in improving research, care, and quality of life for heart patients.



# The Health eHeart Alliance

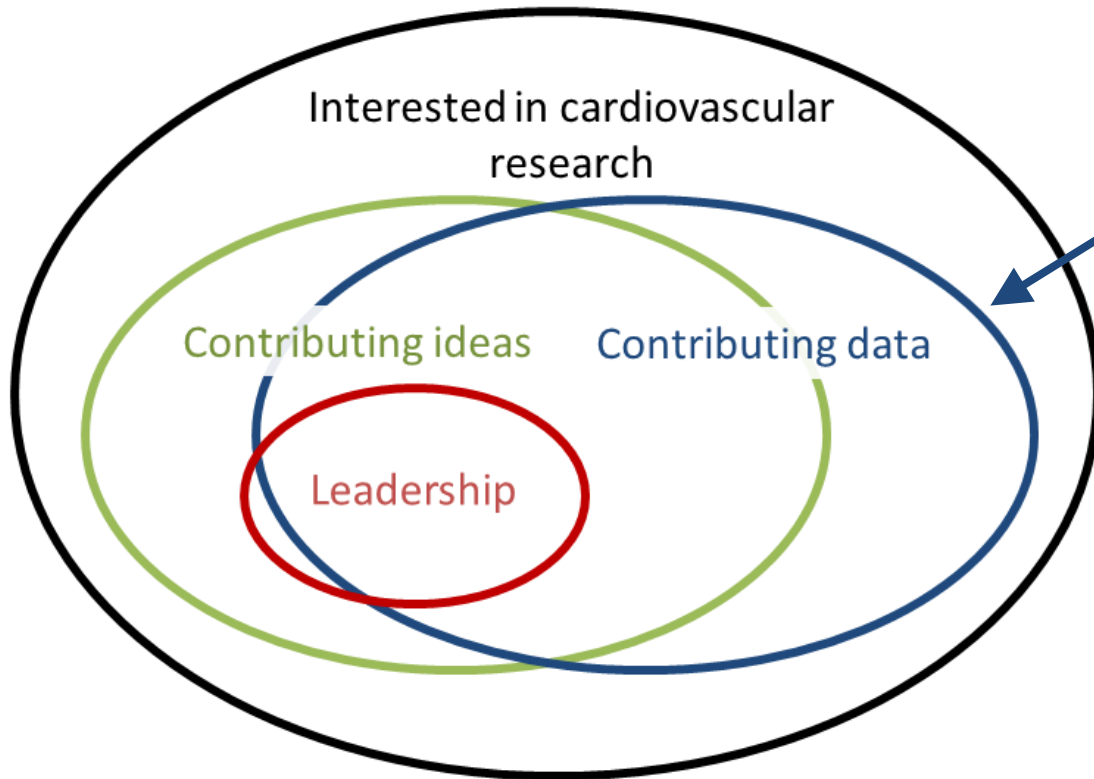
- A “Big Tent” philosophy



**Figure 1. Membership in The Health eHeart Alliance**

The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement

# The Health eHeart Alliance

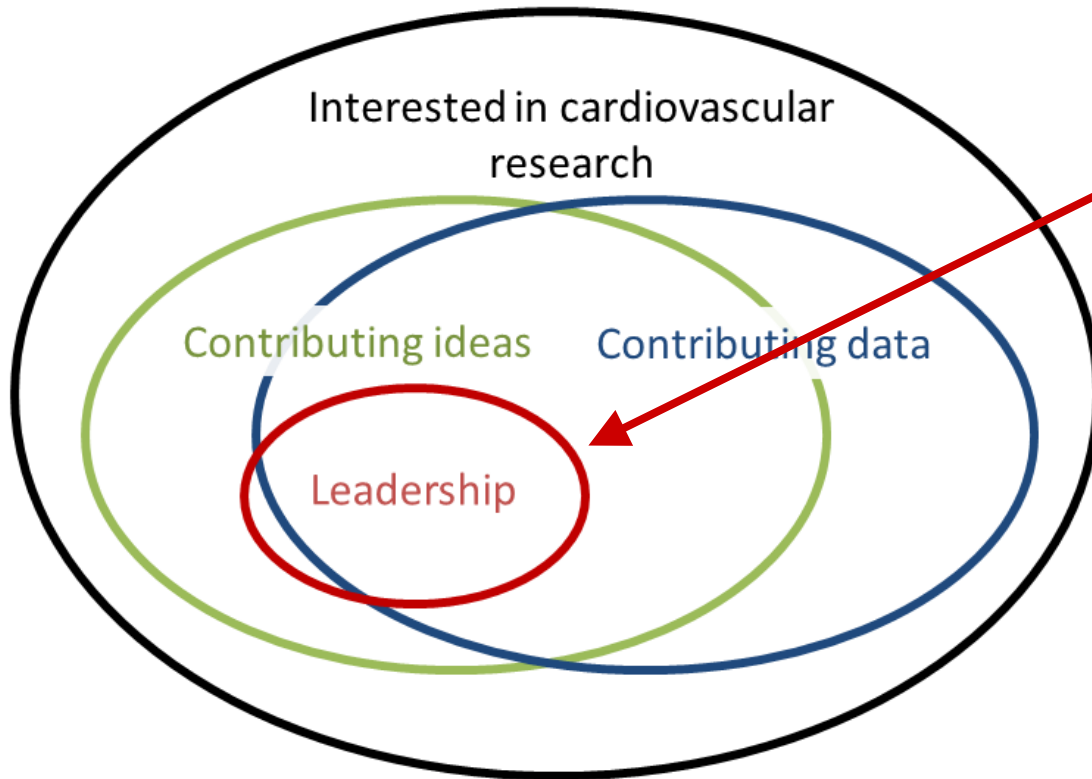


- Includes Health eHeart Study participants...but also anyone else registering interest

**Figure 1. Membership in The Health eHeart Alliance**

The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement

# The Health eHeart Alliance

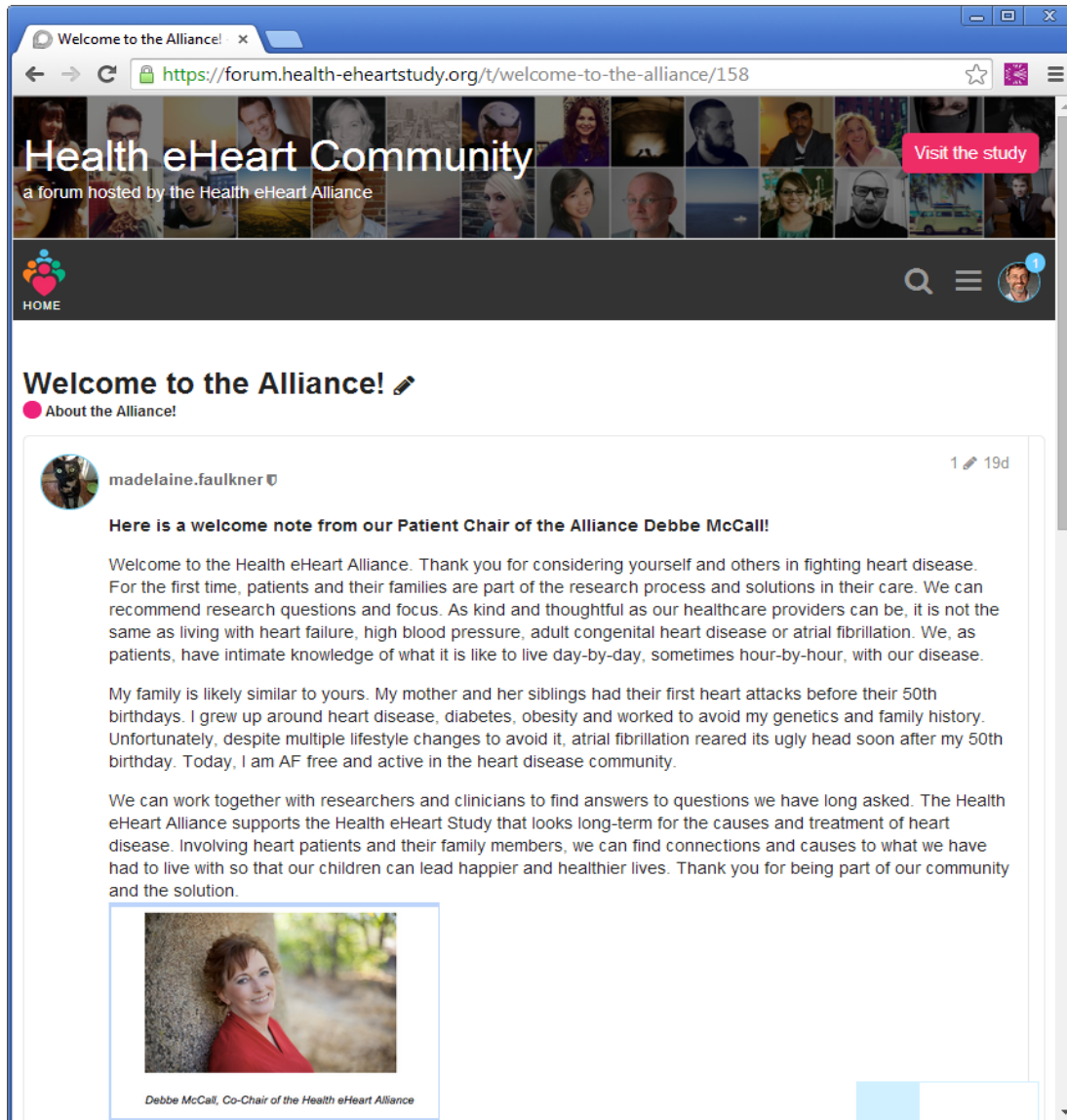


- A Steering Committee chaired by Debbe McCall

**Figure 1. Membership in The Health eHeart Alliance**


The Alliance welcomes anyone declaring their interest in cardiovascular research, defines participation broadly, and expects different levels of engagement

# The Health eHeart Alliance



Welcome to the Alliance! ✎

About the Alliance!


 madelaine.faulkner 1 19d

**Here is a welcome note from our Patient Chair of the Alliance Debbe McCall!**

Welcome to the Health eHeart Alliance. Thank you for considering yourself and others in fighting heart disease. For the first time, patients and their families are part of the research process and solutions in their care. We can recommend research questions and focus. As kind and thoughtful as our healthcare providers can be, it is not the same as living with heart failure, high blood pressure, adult congenital heart disease or atrial fibrillation. We, as patients, have intimate knowledge of what it is like to live day-by-day, sometimes hour-by-hour, with our disease.

My family is likely similar to yours. My mother and her siblings had their first heart attacks before their 50th birthdays. I grew up around heart disease, diabetes, obesity and worked to avoid my genetics and family history. Unfortunately, despite multiple lifestyle changes to avoid it, atrial fibrillation reared its ugly head soon after my 50th birthday. Today, I am AF free and active in the heart disease community.

We can work together with researchers and clinicians to find answers to questions we have long asked. The Health eHeart Alliance supports the Health eHeart Study that looks long-term for the causes and treatment of heart disease. Involving heart patients and their family members, we can find connections and causes to what we have had to live with so that our children can lead happier and healthier lives. Thank you for being part of our community and the solution.

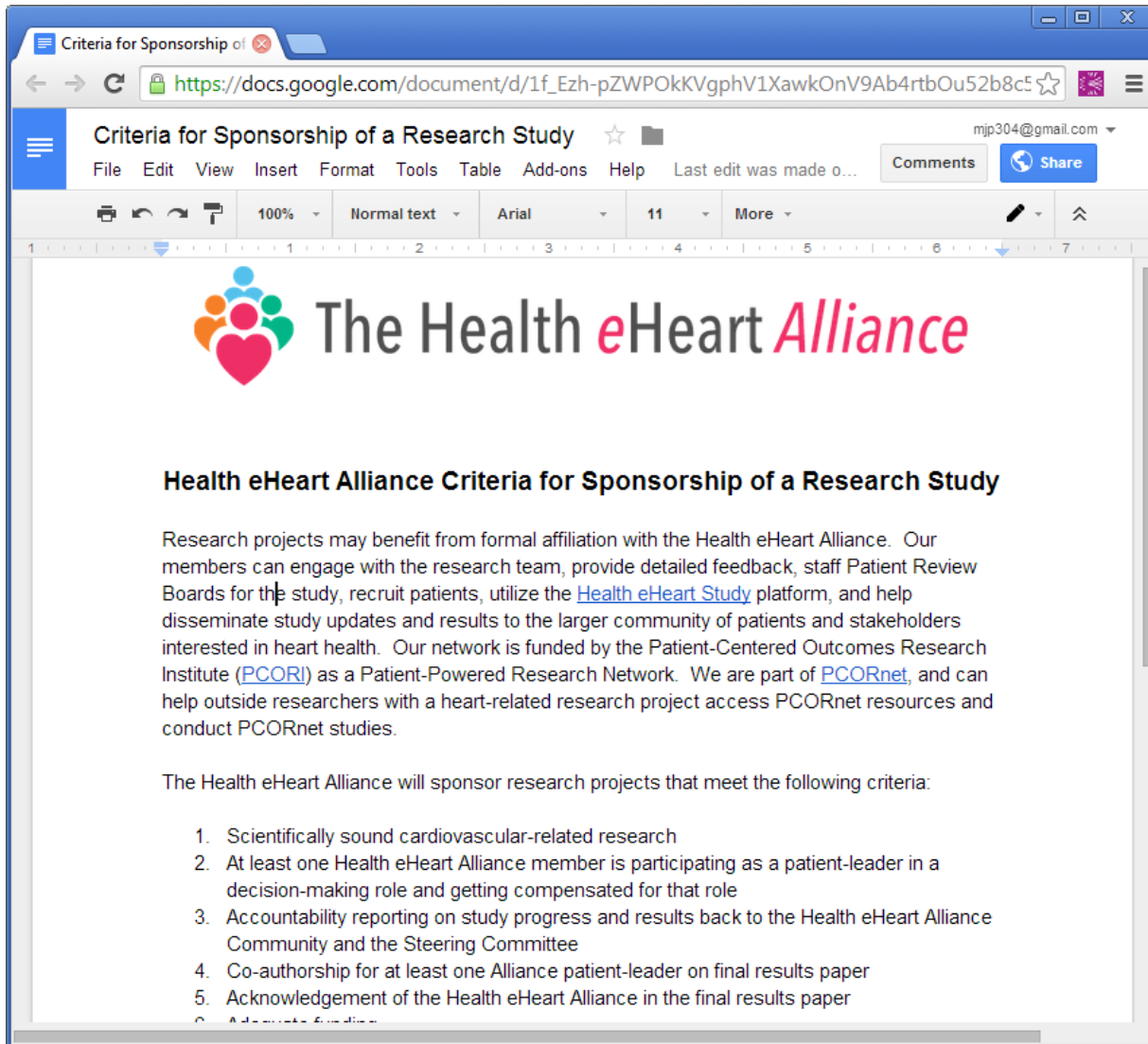


*Debbe McCall, Co-Chair of the Health eHeart Alliance*


A new Community Forum integrated with the Health eHeart Study

# The Health eHeart Alliance

- A set of criteria and procedures for enlisting sponsorship of the Alliance



The screenshot shows a Google Docs document titled "Criteria for Sponsorship of a Research Study". The document content is as follows:

 **The Health eHeart Alliance**

**Health eHeart Alliance Criteria for Sponsorship of a Research Study**

Research projects may benefit from formal affiliation with the Health eHeart Alliance. Our members can engage with the research team, provide detailed feedback, staff Patient Review Boards for the study, recruit patients, utilize the [Health eHeart Study](#) platform, and help disseminate study updates and results to the larger community of patients and stakeholders interested in heart health. Our network is funded by the Patient-Centered Outcomes Research Institute ([PCORI](#)) as a Patient-Powered Research Network. We are part of [PCORnet](#), and can help outside researchers with a heart-related research project access PCORnet resources and conduct PCORnet studies.

The Health eHeart Alliance will sponsor research projects that meet the following criteria:

1. Scientifically sound cardiovascular-related research
2. At least one Health eHeart Alliance member is participating as a patient-leader in a decision-making role and getting compensated for that role
3. Accountability reporting on study progress and results back to the Health eHeart Alliance Community and the Steering Committee
4. Co-authorship for at least one Alliance patient-leader on final results paper
5. Acknowledgement of the Health eHeart Alliance in the final results paper
6. Adequate funding

# The Health eHeart Alliance

- A growing list of major research projects

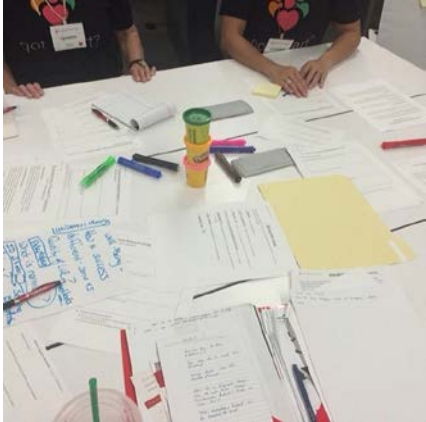
The screenshot shows a Google Docs spreadsheet with the following data:

#	WG	SC	Info link	PI	Alliance Rep	Status	Title
1	n/a	3/12/2015	<a href="#">Link</a>	Matt Roe	Adaptors	FUNDED, CONTRACT PE	ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits
2	n/a	3/12/2015	<a href="#">Link</a>	Eric Velasquez	Heidi Dohse	Not Funded	TRANSFORM-HF - a randomized trial of torsemide vs. furosemide f
3	1/24/2015	3/12/2015	<a href="#">Link</a>	Kirsten Bibbins-Domingo	n/a	Not Funded	MATCH-CA (Bibbins-Domingo grant on hypertension and disparities)
4	9/10/2015	9/10/2015	<a href="#">Link</a>	Karen Margolis	Pt-Advisory Board	Submitted	A Practical Comparison Between Telehealth vs. Clinic Care for Treating H
5	9/10/2015	9/10/2015	<a href="#">Link</a>	Andy Nierenberg	Heidi Dohse	Submitted	Healthy Hearts Healthy Minds
6	9/10/2015	9/10/2015	<a href="#">Link</a>	Heather Kaplan	Kathi Sigona	Submitted	N of 1 Study for Atrial Fibrillation Triggers
7	n/a	11/12/2015	<a href="#">Link</a>	Christopher Schmid	Kathi Sigona	Submitted	N of 1 Methodology Study
8	1/25/2016	1/14/2016	<a href="#">Link</a>	Beverly Green	TBN	To be submitted soon	BP-CHECK (Blood Pressure Checks and Hypertension Diagnosis)

# Patient-Centered Reviews

- Example: Hypertension telehealth study - Karen Margolis
  - Proposed to Alliance
  - 8000 Health eHeart Study participants with HTN emailed
  - 1000 clicked through to a Google Doc
  - Hundreds participated in simultaneous editing and commenting (broke Google docs!)
- Conference call and surveys for patient input, and strong Alliance support for the grant application

# Patient-Powered Research





# Patient-Powered Research

- Triggers of MI
- N of 1 toolkit for statin decliners → CVD risk, satisfaction
- N of 1 toolkit for paroxysmal afib → QOL
- Online support groups for newly diagnosed afib
- Qualitative study of transitions in care, role of data
- Using activity monitors to increase activity in CVD patients
- Sharing mental health issues with cardiologists
- Improving “success in life” among young stroke patients

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# HeH Alliance and PCORnet

- Health eHeart Alliance is PCORnet's cardiovascular-focused patient-powered research network
- Opportunities for research are immense
  - Engaged patients in PPRNs
  - 100 million recruitable patients with EHR data in CDRNs
  - HeH Study provides a way to engage these patients and collect PROs and mHealth data

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**Learn more at 4pm today!**

# We want YOU!



Come to our 4pm PCORnet Session later today  
Propose PCORnet Research and get grant application support  
Call for Proposals: <https://www.bit.ly/1VHmukD>

Join the Study: <https://www.health-eheartstudy.org/>  
and/or the Conversation Forum: [/community](#)

Analyze Health eHeart Study data  
Use Health eHeart (or our NIH-funded white-labeled platform)  
to collect mHealth data for your research project  
[Email me, Jeff Olgin or Greg Marcus](#)



# Volunteer bias

	<u>US pop</u> NHANES <u>n=6,113</u>	<u>Health eHeart</u>		
		All <u>n=26,982</u>	eVisit done + <u>n=16,501</u>	Fitbit <u>n=1,276</u>
Age, mean	47	51	52	49
% Female	52%	75%	74%	68%
% AA	12%	6%	4%	2%
% College+	29%		71%	74%

# Volunteer bias

- Similar patterns of response in other internet-based studies

Comparison of the sociodemographic characteristics of the large NutriNet-Santé e-cohort with French Census data: the issue of volunteer bias revisited

Valentina A Andreeva,<sup>1</sup> Benoît Salanave,<sup>2</sup> Katia Castetbon,<sup>2</sup> Valérie Deschamps,<sup>2</sup> Michel Vernay,<sup>2</sup> Emmanuelle Kesse-Guyot,<sup>1</sup> Serge Hercberg<sup>1,2,3</sup>

78% female, 65% post-secondary education



# HeH Alliance and PCORnet

- PCORnet Cardiovascular Health Collaborative Research Group (CVH CRG)
  - Initial focus on HTN, CHF, Women with Chest Pain
    - Bluetooth BP cuffs → Better/faster BP Control?
    - Precision BP medication prescribing?
    - BP Control “Laboratory” in PCORnet?
    - EHR data → Early warning system for CHF hosp?
    - 6MWT app for CHF home self-monitoring?
    - Does atherosclerosis Rx or ACE-I help women with CP?
  - Propose your own project!

# HeH Alliance and PCORnet

- PCORnet Cardiovascular Health Collaborative Research Group (CVH CRG)
  - Come to 4pm session today to hear more and get engaged!
    - Travel \$ and support for PCORI-style applications
    - Call for Proposals: <https://www.bit.ly/1VHmukD>

# Health eHeart → Health ePeople

- U2C contract from NIH: Mobilizing Research
  - <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-15-129.html>
  - General platform for gathering mHealth data from research participants
  - Open up broadly to research community
    - Coming this Summer!

# Pragmatic Technology-Enabled Randomized Controlled Trials

- eRCTs should be able to:
  - Approach, consent, and enroll over the internet
  - Use online surveys for self-reported data
  - Use electronic health records for finding patients and collecting health measurements and outcomes
  - Use sensors to collect and transmit real-time/real-life data, deliver novel interventions
  - Use smartphone geolocation and movement pattern data to detect hospitalization events
  - Use online social networks and forum technology to collect social data, engage ppts



### Specific questions from Dr. Margolis and colleagues

[What about those who do not have high blood pressure, but are always 'borderline',  
~~eachatplease type your suggestions here]~~

I think discussing diet and exercise are important, as well as other natural means of controlling high BP. I'd like to know all about fluctuations in BP levels - why is it sometimes high, sometimes low, sometimes borderline? Information helps a person stick to proper procedures to help their BP stay at optimum levels.  
~~isesike>nta icizercise are important wxe~~

1. **Besides seeing how much blood pressure changes in our study, what other "outcomes" should we measure that are important to you? Some examples of other outcomes might be avoiding medication side effects, avoiding interference with work or other responsibilities, or having treatments that are simple to do.**

4. Knowing which treatment modality is more effective is a pretty good outcome to start with. It would also be interesting to know what kinds of patients respond better to the different modalities, ie do women respond to one better than men, or does the different kind of hypertension respond better, essential vs renovascular.

There somehow should be a more accurate way to take blood pressure. One way to lower it is to lose weight.

You only get improved blood pressure WHILE you're losing weight. Not a good treatment for long-term use....

**Comment [7]:** So far I haven't seen one word about relaxation techniques and their lowering effect on BP. When I first was diagnosed in 1971, I went to a BP clinic where they emphasized relaxation techniques. I'm on medication, but I can lower my BP several points with meditation and relaxation techniques. Are these no longer taught?

**Comment [8]:** Why not also measure blood oxygen levels? It's easy to do and it might be a factor for some patients.

**Formatted:** No bullets or numbering

**Comment [9]:** Outcomes that might not be "by the numbers" could include better sleep, ability to do moderate exercise, fewer headaches.

# Disclosures

Research infrastructure grants from PCORI and NIH supporting the Health eHeart Alliance and the Health ePeople Resource for mHealth data collection