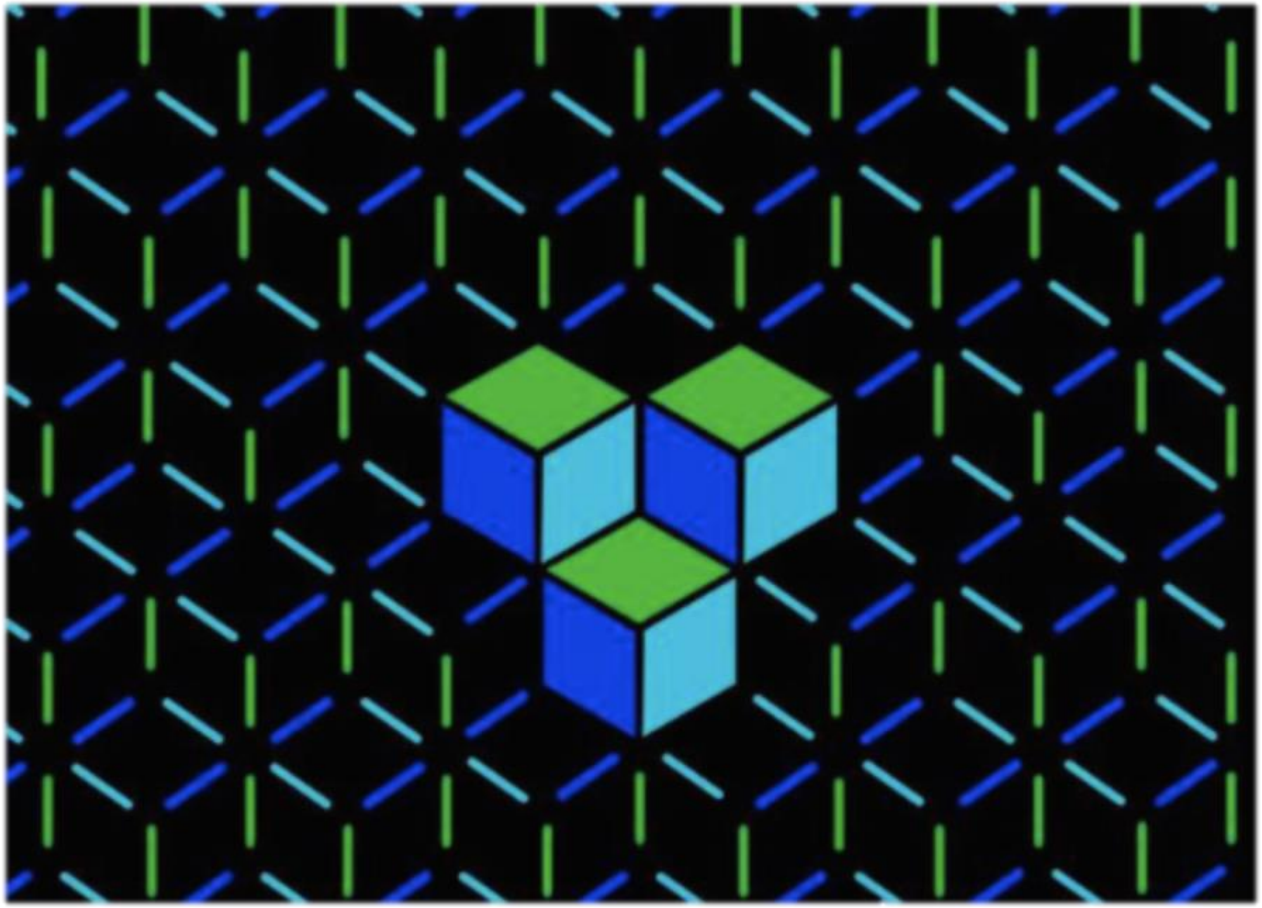
Innovation in Informed Consent
Sage Bionetworks Toolkit



UBC REB retreat, 21 Oct 2015
Christine Suver, PhD

Introductions

Why Sage Bionetworks?

Enabling large scale collaborative science

We believe in a world where **biomedical research** is conducted in an **open, collaborative** way, where not only the current **guilds of experts**, but **each of us** can contribute to making better, faster, relevant discoveries.

The two problems

- **The way we generate clinical data**
- **The way we analyze clinical data**

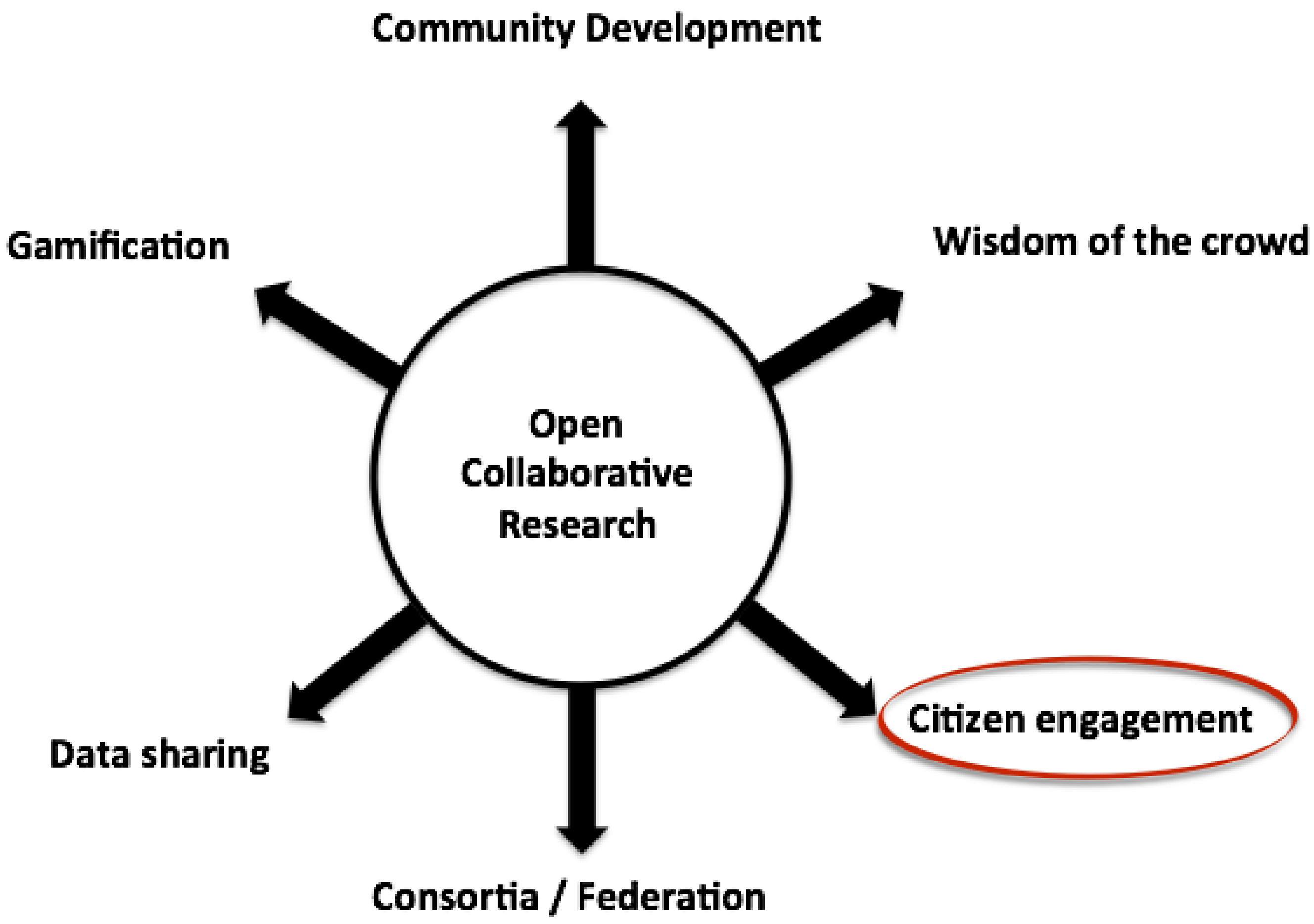
Clinical Data Generation

- Not enough people
- Not enough time points per person
- Not enough data components per time point
- Not readable by machines

Clinical Data Analysis

- **We hoard data**
- **We don’t bother to prepare for its reuse**
- **We don’t annotate enough for others to use**
- **We don’t get rewarded for sharing it**

sage bionetworks



Community Development

Gamification

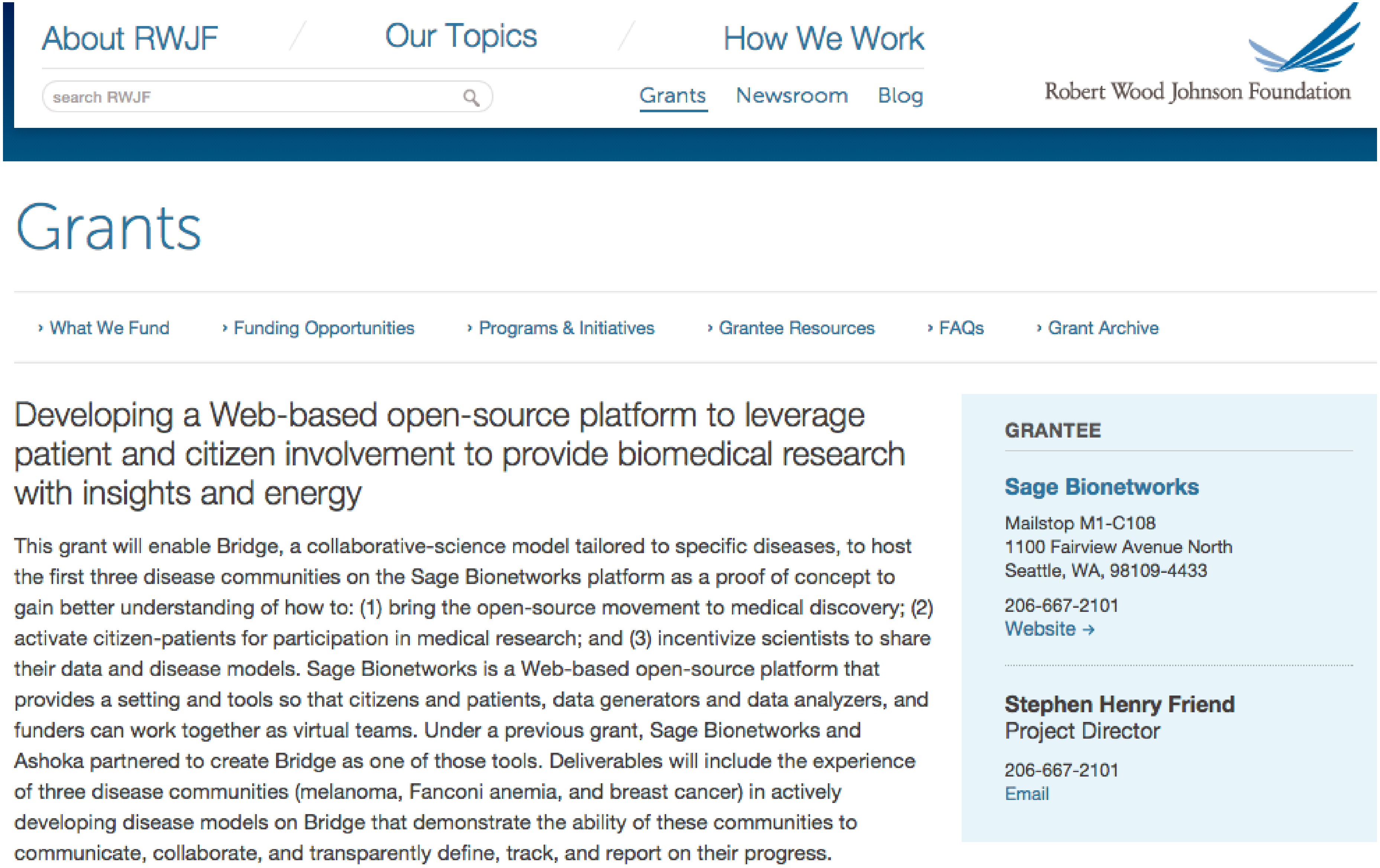
Wisdom of the crowd

Open Collaborative Research

Citizen engagement

Data sharing

Consortia / Federation



Grants

Developing a Web-based open-source platform to leverage patient and citizen involvement to provide biomedical research with insights and energy

This grant will enable Bridge, a collaborative-science model tailored to specific diseases, to host the first three disease communities on the Sage Bionetworks platform as a proof of concept to gain better understanding of how to: (1) bring the open-source movement to medical discovery; (2) activate citizen-patients for participation in medical research; and (3) incentivize scientists to share their data and disease models. Sage Bionetworks is a Web-based open-source platform that provides a setting and tools so that citizens and patients, data generators and data analyzers, and funders can work together as virtual teams. Under a previous grant, Sage Bionetworks and Ashoka partnered to create Bridge as one of those tools. Deliverables will include the experience of three disease communities (melanoma, Fanconi anemia, and breast cancer) in actively developing disease models on Bridge that demonstrate the ability of these communities to communicate, collaborate, and transparently define, track, and report on their progress.

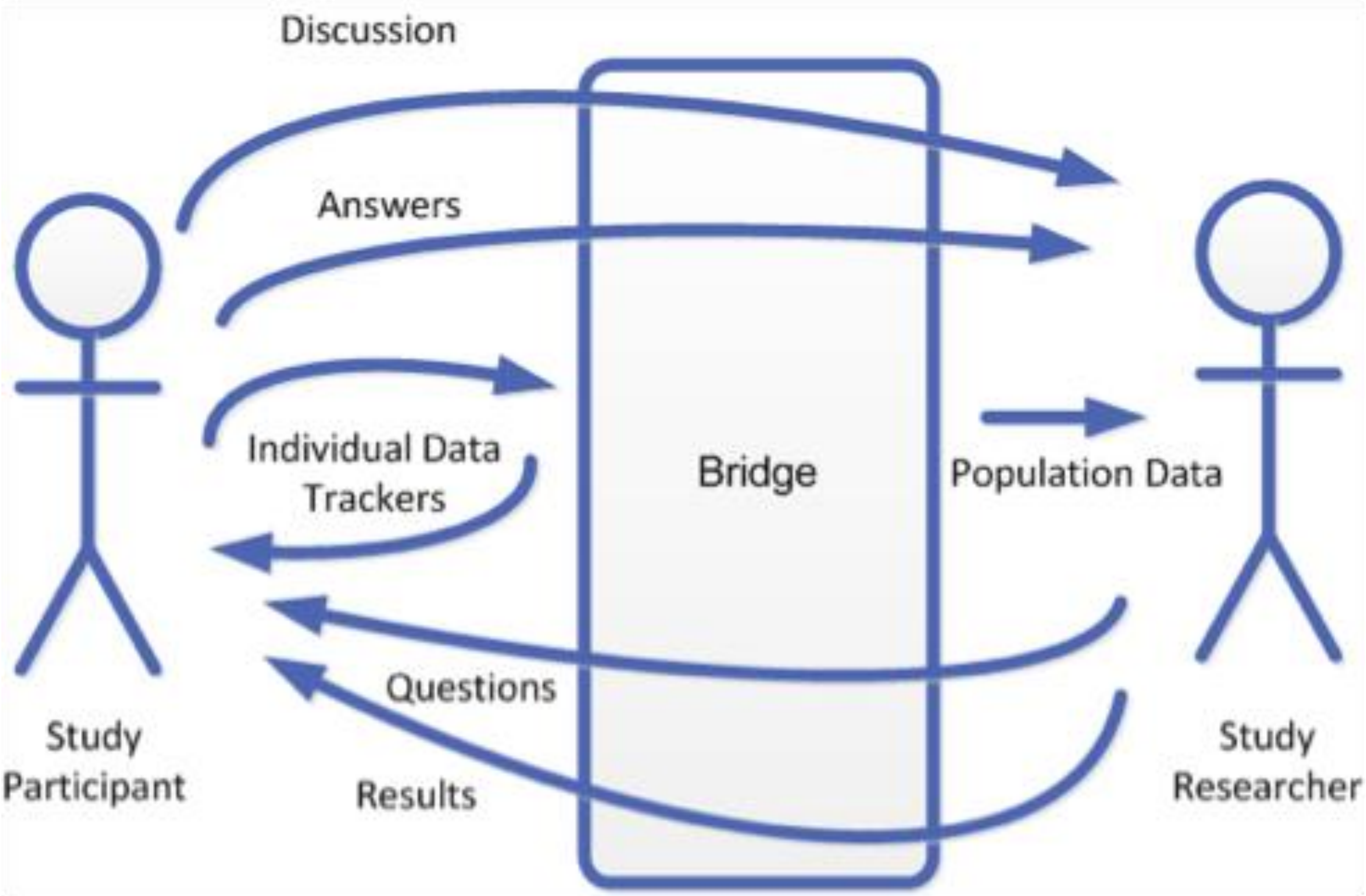
GRANTEE

Sage Bionetworks
Mailstop M1-C108
1100 Fairview Avenue North
Seattle, WA, 98109-4433

206-667-2101
Website →

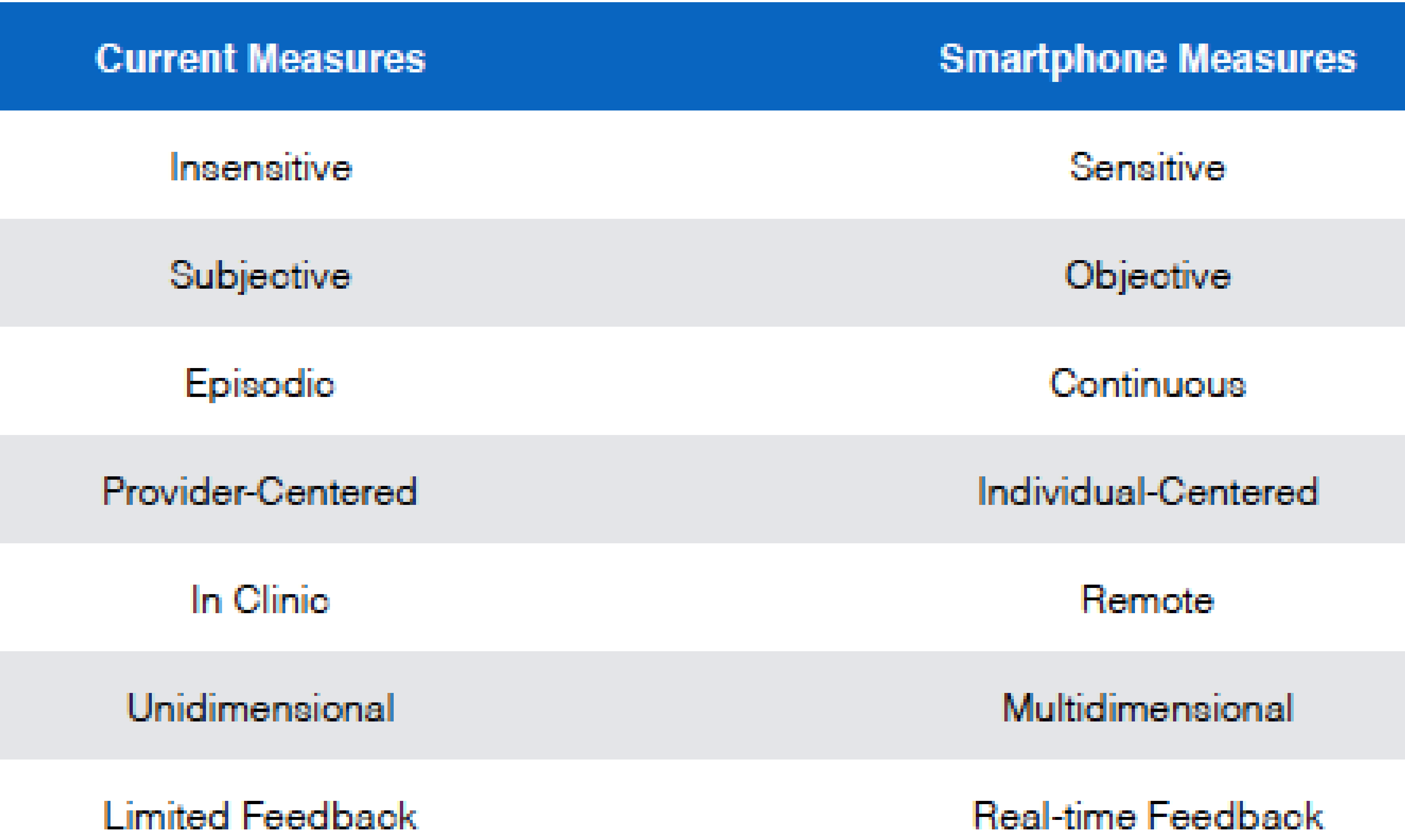
Stephen Henry Friend
Project Director

206-667-2101
Email


Discussion
Answers
Individual Data Trackers
Bridge
Population Data
Questions
Results
Study Participant
Study Researcher

Whether you are healthy or living with Parkinson's, help provide the voice information needed to build a system to screen for and monitor the symptoms of this debilitating disease. All you need to do: make a low-cost, anonymous, three-minute phone call.

🇺🇸	USA	1-857-284-8035
🇧🇷	Brazil	11 3957-0683
🇲🇽	Mexico	55-41703631
🇬🇧	UK	01865 521168
🇪🇸	Spain	91 123 4793
🇦🇷	Argentina	11.5252.8741
🇨🇦	Canada	1-647-931-5976



Current Measures	Smartphone Measures
Insensitive	Sensitive
Subjective	Objective
Episodic	Continuous
Provider-Centered	Individual-Centered
In Clinic	Remote
Unidimensional	Multidimensional
Limited Feedback	Real-time Feedback

from 1800 to 100,000

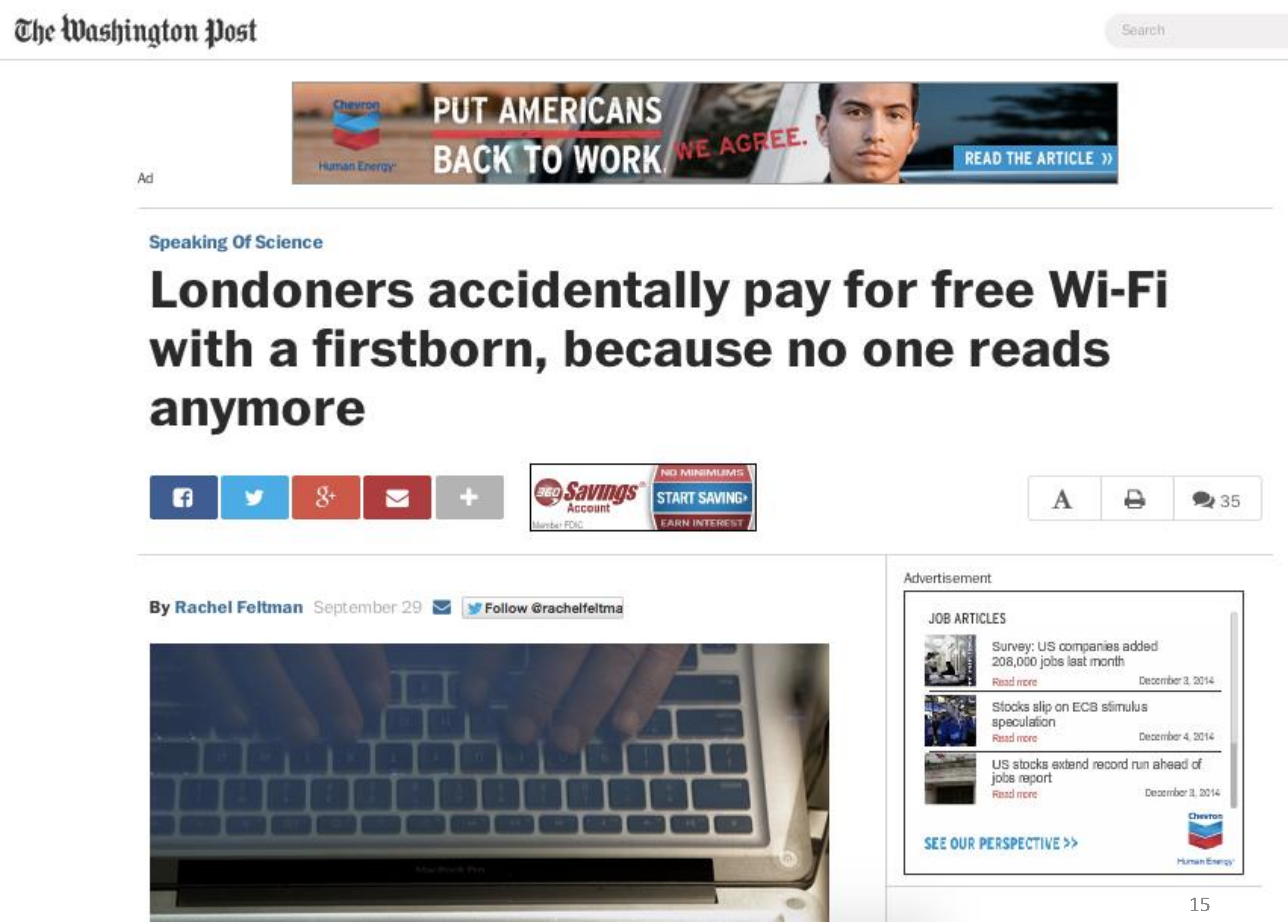
…but research through phones requires additional regulatory and ethical tools

Radical honesty

>

Radical restrictions

Can we make consent informed in a mobile context?



Speaking Of Science

Londoners accidentally pay for free Wi-Fi with a firstborn, because no one reads anymore

By **Rachel Feltman** September 29

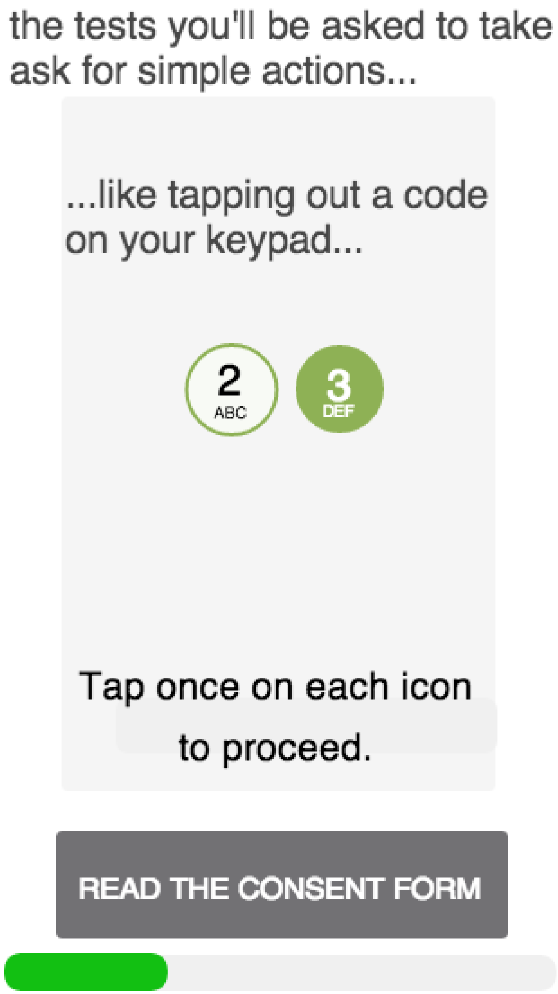
]

Informed consent
A process with many elements

Starting point

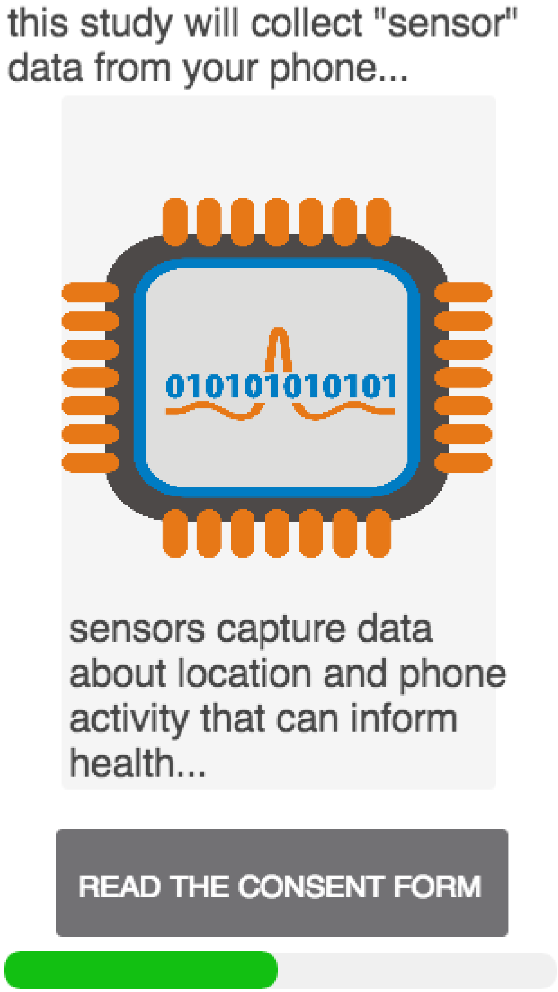
- **Create a self-paced consent**
- **Assessment of understanding**
- **Minimal risk research**
- **Testing iPhone sensors against validated assessment for phenotype**

Initial metaphor

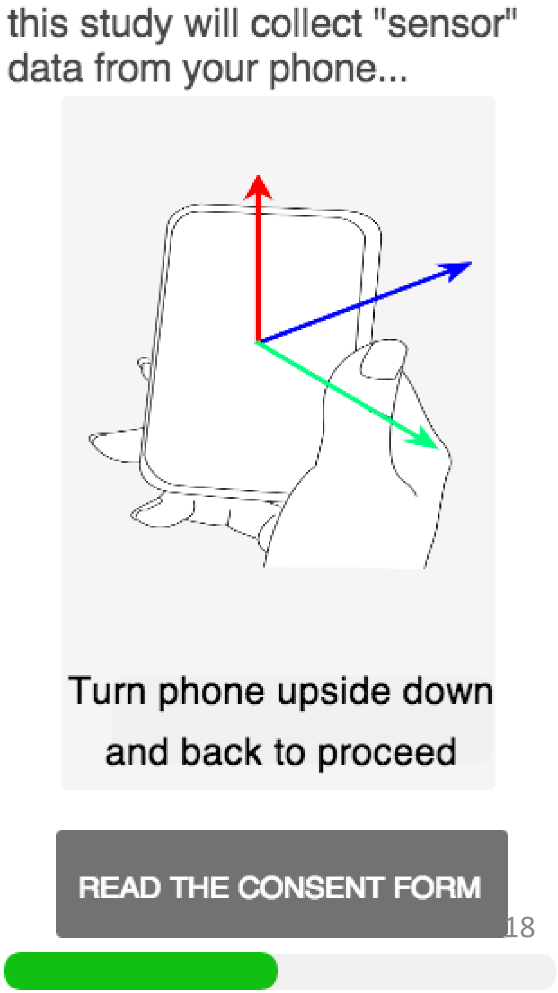

the tests you'll be asked to take ask for simple actions...

...like tapping out a code on your keypad...

Tap once on each icon to proceed.


this study will collect "sensor" data from your phone...

sensors capture data about location and phone activity that can inform health...


this study will collect "sensor" data from your phone...

Turn phone upside down and back to proceed

A software framework
made specifically for
medical research

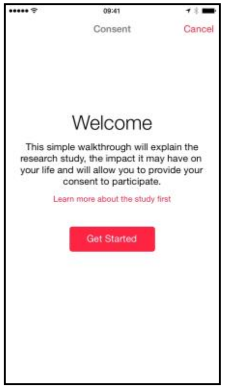
ResearchKit

It's open source.
So the world can
make the most of it.

participant-centered consent

- tiered information access by participants
- ‘pictorial’ dominant on first information tier
- text dominant on second information tier
- require perfect score on short assessment

The consent steps

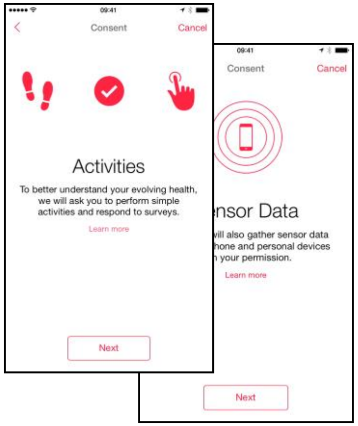


Welcome

This simple walkthrough will explain the research study, the impact it may have on your life and will allow you to provide your consent to participate.

Learn more about the study first

Welcome



Activities

To better understand your evolving health, we will ask you to perform simple activities and respond to surveys.

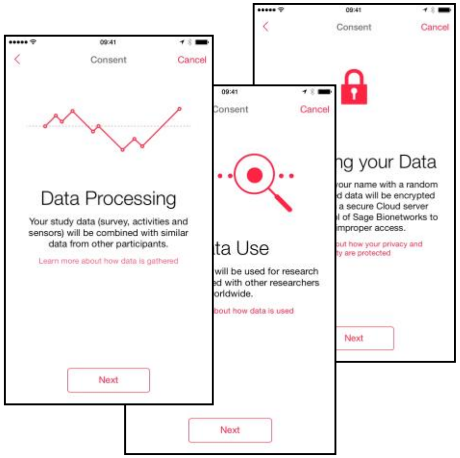
Learn more

nsor Data

ill also gather sensor data
hone and personal devices
your permission.

Learn more

Describe the research



Data Processing

Your study data (survey, activities and sensors) will be combined with similar data from other participants.

Learn more about how data is gathered

ta Use

will be used for research
ed with other researchers
orldwide.

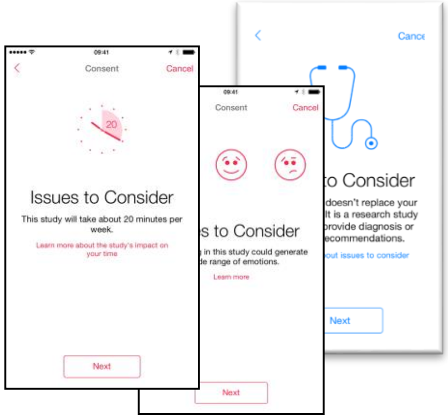
bout how data is used

ng your Data

your name with a random
d data will be encrypted
a secure Cloud server
l of Sage Bionetworks to
improper access.

ut how your privacy and
ty are protected

Describe data handling and use



Issues to Consider

This study will take about 20 minutes per week.

Learn more about the study's impact on your time

s to Consider

in this study could generate
de range of emotions.

Learn more

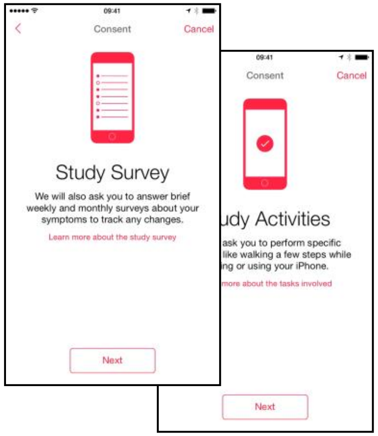
to Consider

doesn't replace your
It is a research study
provide diagnosis or
ecommendations.

out issues to consider

Impact on your life /

Issues to consider



Study Survey

We will also ask you to answer brief weekly and monthly surveys about your symptoms to track any changes.

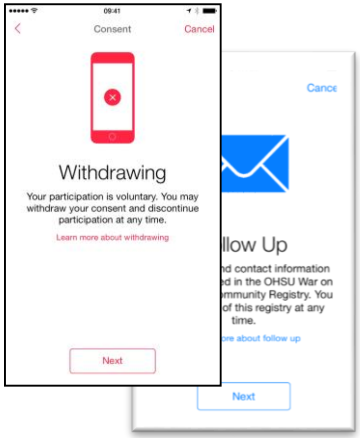
Learn more about the study survey

udy Activities

ask you to perform specific
like walking a few steps while
ing or using your iPhone.

more about the tasks involved

What is involved



Withdrawing

Your participation is voluntary. You may withdraw your consent and discontinue participation at any time.

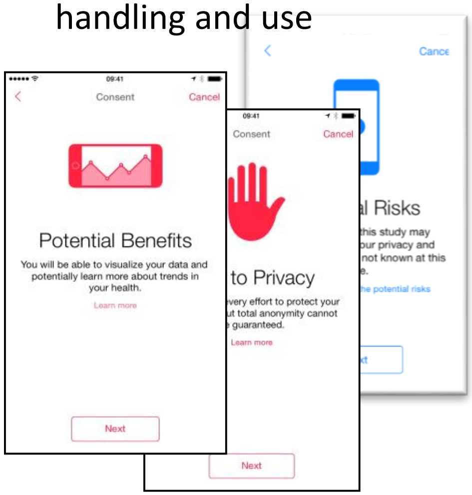
Learn more about withdrawing

llow Up

nd contact information
ed in the OHSU War on
mmunity Registry. You
of this registry at any
time.

ore about follow up

Your rights



Potential Benefits

You will be able to visualize your data and potentially learn more about trends in your health.

Learn more

to Privacy

very effort to protect your
ut total anonymity cannot
guaranteed.

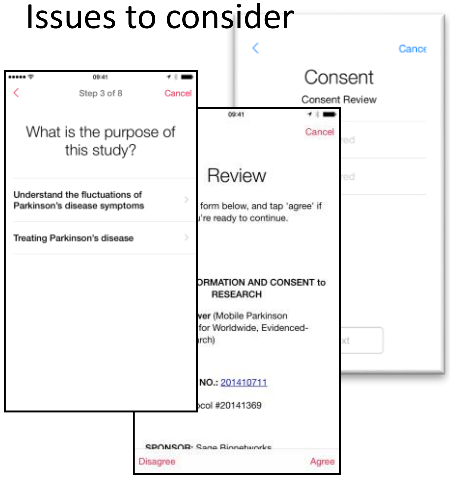
Learn more

l Risks

this study may
our privacy and
not known at this
e.

he potential risks

Potential risks and benefits



What is the purpose of this study?

Understand the fluctuations of Parkinson's disease symptoms

Treating Parkinson's disease

Review

form below, and tap 'agree' if
u're ready to continue.

ORMATION AND CONSENT to RESEARCH

wer (Mobile Parkinson
for Worldwide, Evidenced-
rch)

NO.: 201410711

ocol #20141369

SPONSOR: Sage Bionetworks

Consent

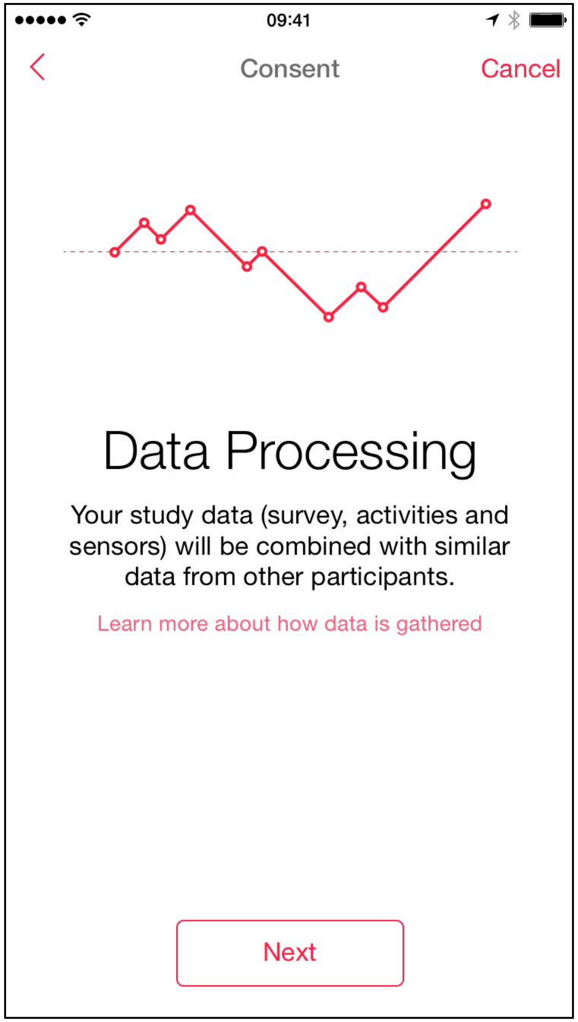
Consent Review

ed

ed

Comprehension- Review & Consent

Screens are organized in consistent areas



Data Processing

Your study data (survey, activities and sensors) will be combined with similar data from other participants.

Navigation

Visual Information area
Graphics demonstrate and reinforce the information provided in text.

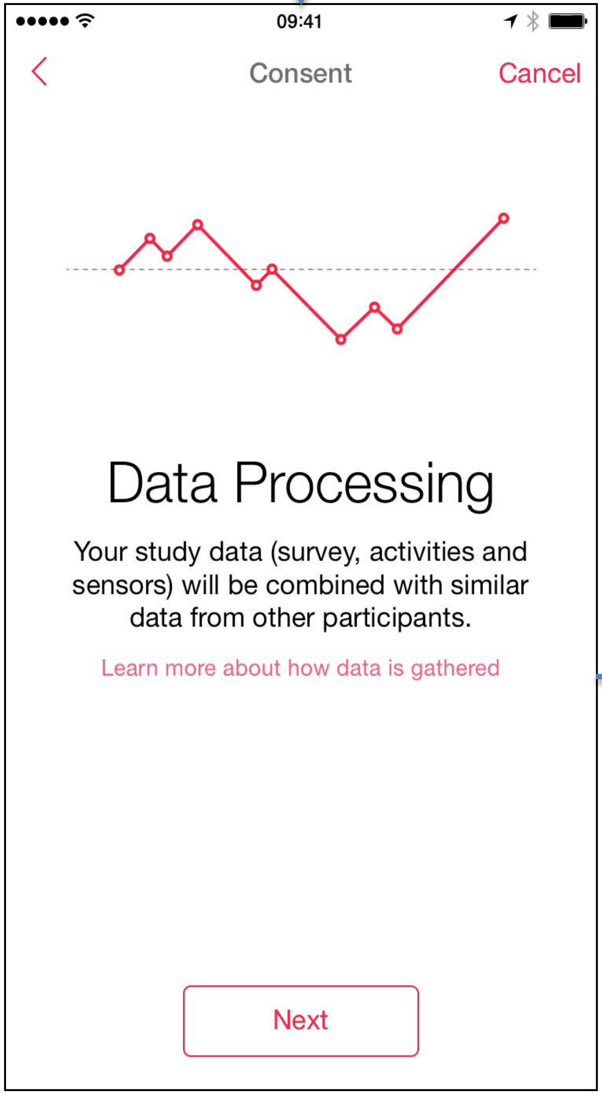
Main Concept

Text Information area

Learn more links
Opens to detailed text from the consent document.

Instruction area

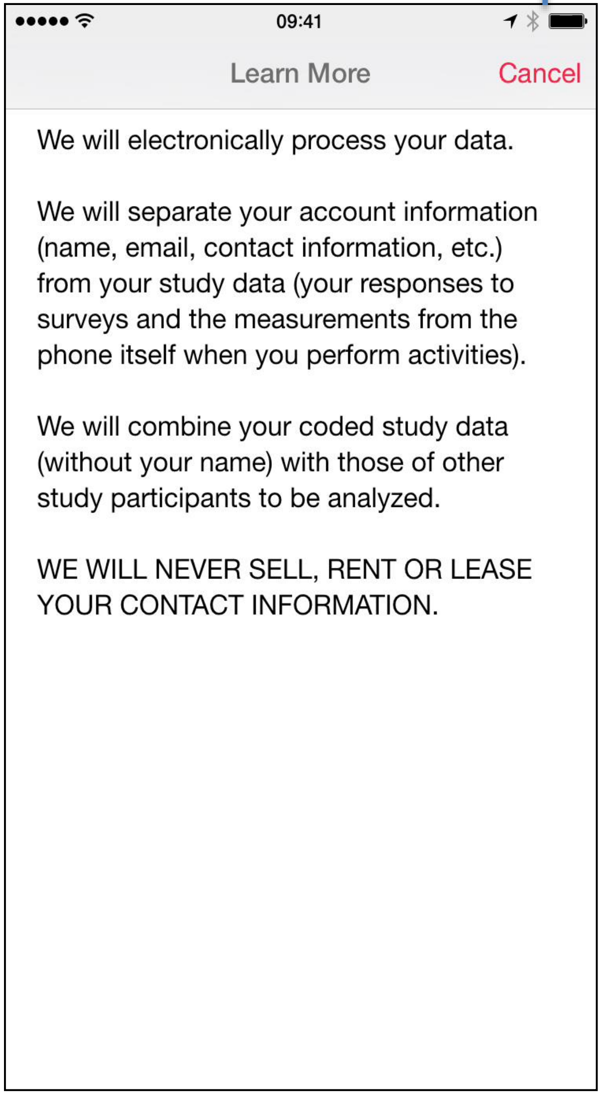
Navigation to/from Learn More screen- Reinforces concept



Data Processing

Your study data (survey, activities and sensors) will be combined with similar data from other participants.

Learn more about how data is gathered

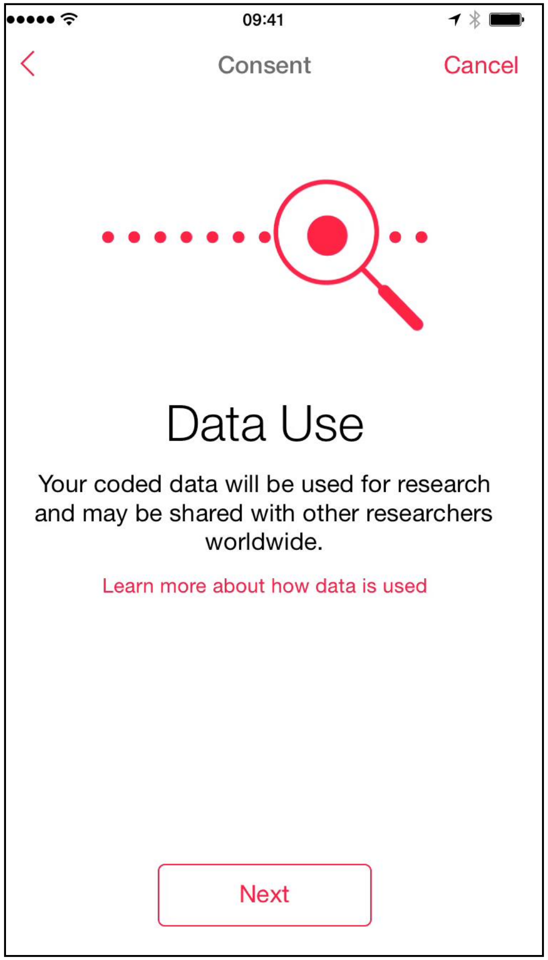


We will electronically process your data.

We will separate your account information (name, email, contact information, etc.) from your study data (your responses to surveys and the measurements from the phone itself when you perform activities).

We will combine your coded study data (without your name) with those of other study participants to be analyzed.

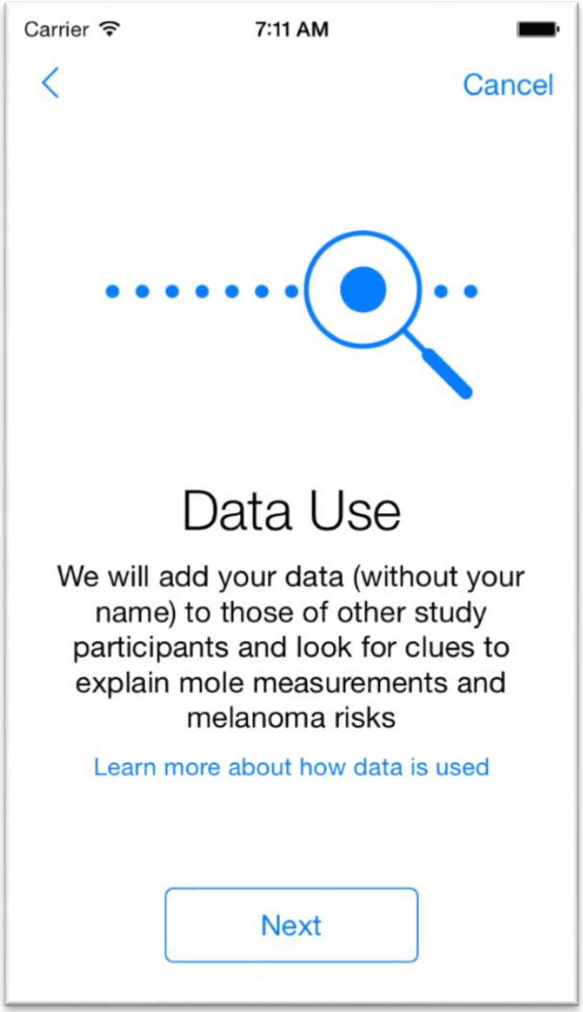
WE WILL NEVER SELL, RENT OR LEASE YOUR CONTACT INFORMATION.



Data Use

Your coded data will be used for research and may be shared with other researchers worldwide.

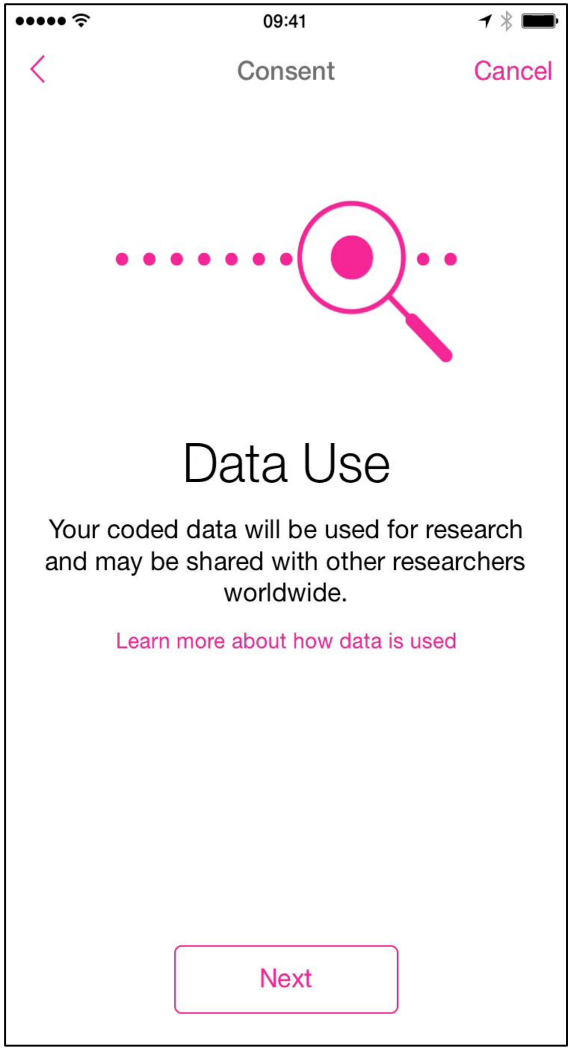
Learn more about how data is used



Data Use

We will add your data (without your name) to those of other study participants and look for clues to explain mole measurements and melanoma risks

Learn more about how data is used



Data Use

Your coded data will be used for research and may be shared with other researchers worldwide.

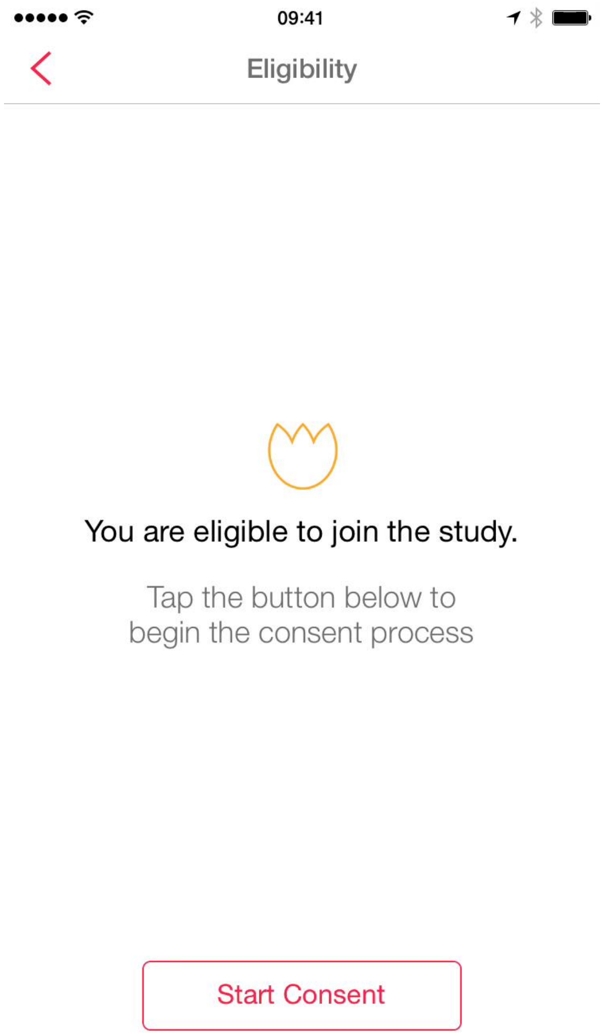
Learn more about how data is used

Eligibility criteria must be well defined and interactive

Are you 18 or older?

Do you live in the United States of America?

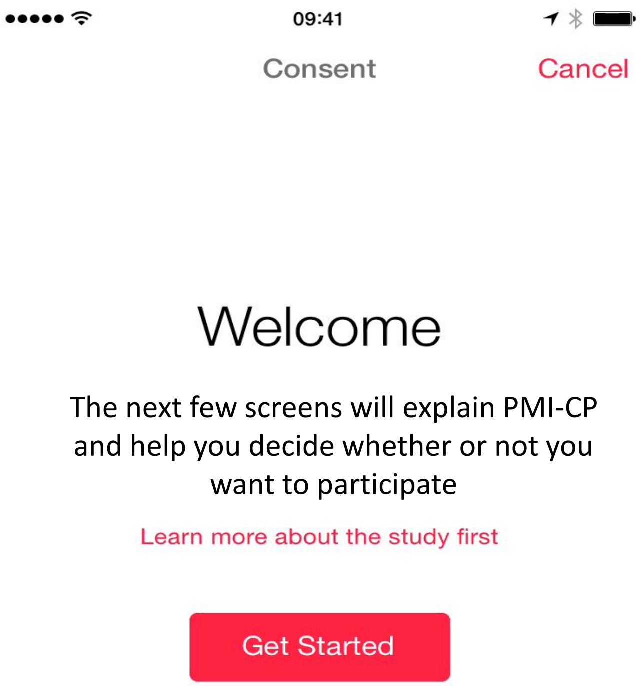
Are you comfortable reading and writing on your iPhone in English?



You are eligible to join the study.

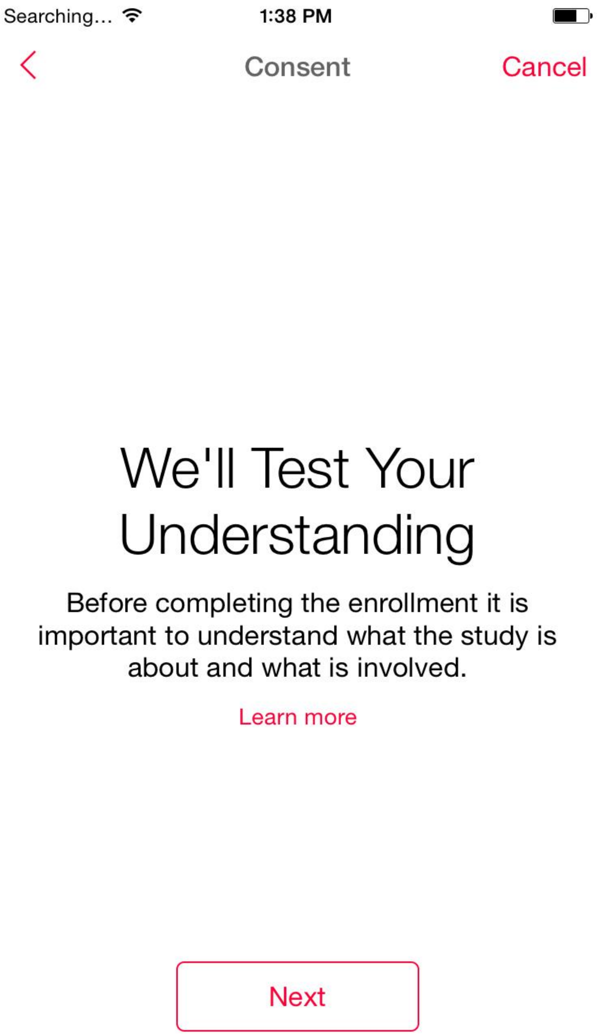
Tap the button below to begin the consent process

Purpose of the Informed consent process



Welcome

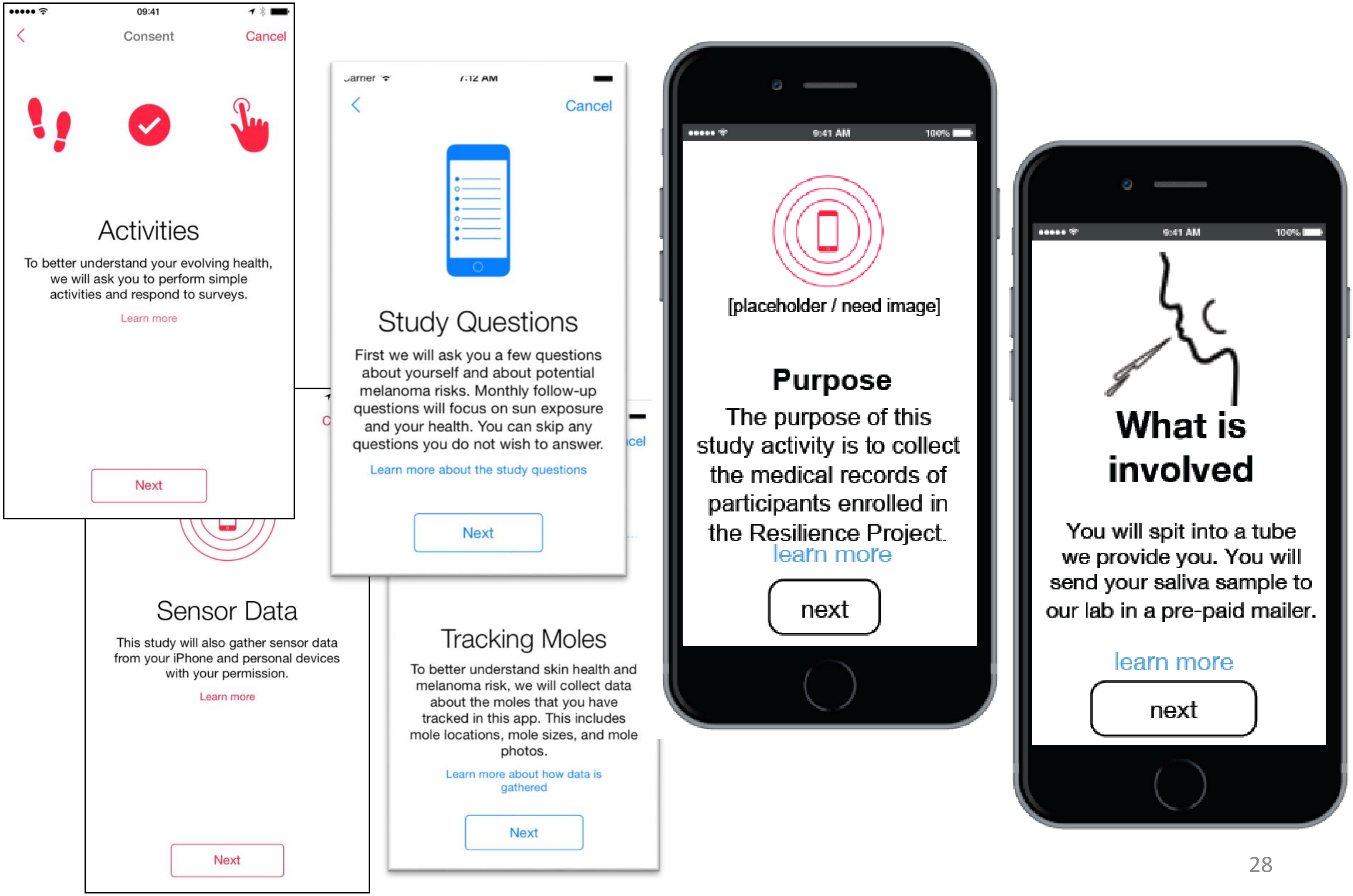
The next few screens will explain PMI-CP and help you decide whether or not you want to participate



We'll Test Your Understanding

Before completing the enrollment it is important to understand what the study is about and what is involved.

What will happen during the study?



09:41

Consent

Cancel

Activities

To better understand your evolving health, we will ask you to perform simple activities and respond to surveys.

Learn more

Next

Sensor Data

This study will also gather sensor data from your iPhone and personal devices with your permission.

Learn more

Next

7:12 AM

Cancel

Study Questions

First we will ask you a few questions about yourself and about potential melanoma risks. Monthly follow-up questions will focus on sun exposure and your health. You can skip any questions you do not wish to answer.

Learn more about the study questions

Next

Tracking Moles

To better understand skin health and melanoma risk, we will collect data about the moles that you have tracked in this app. This includes mole locations, mole sizes, and mole photos.

Learn more about how data is gathered

Next

9:41 AM 100%

[placeholder / need image]

Purpose

The purpose of this study activity is to collect the medical records of participants enrolled in the Resilience Project.

learn more

next

9:41 AM 100%

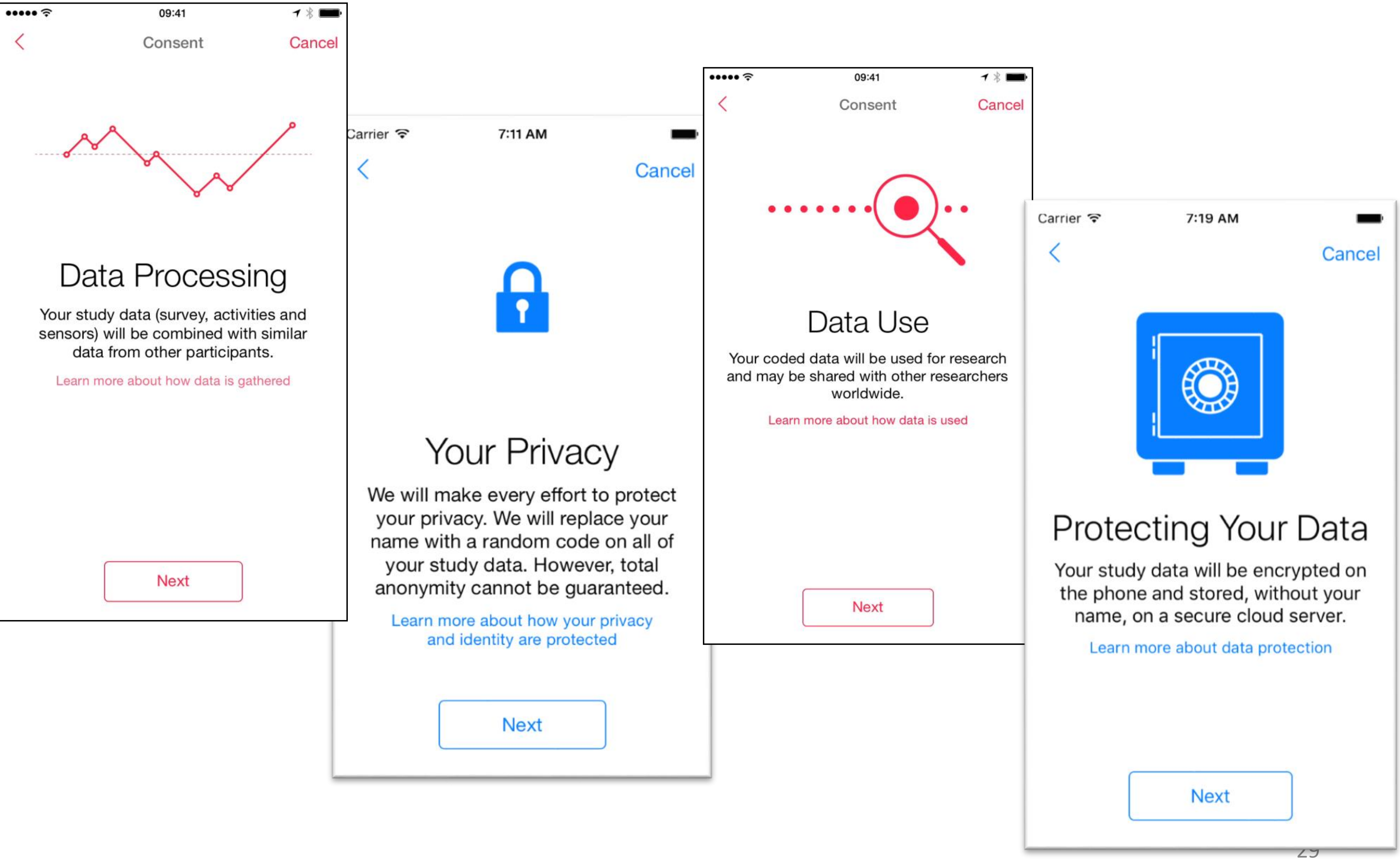
What is involved

You will spit into a tube we provide you. You will send your saliva sample to our lab in a pre-paid mailer.

learn more

next

Data handling



Data Processing

Your study data (survey, activities and sensors) will be combined with similar data from other participants.

Learn more about how data is gathered

Your Privacy

We will make every effort to protect your privacy. We will replace your name with a random code on all of your study data. However, total anonymity cannot be guaranteed.

Learn more about how your privacy and identity are protected

Data Use

Your coded data will be used for research and may be shared with other researchers worldwide.

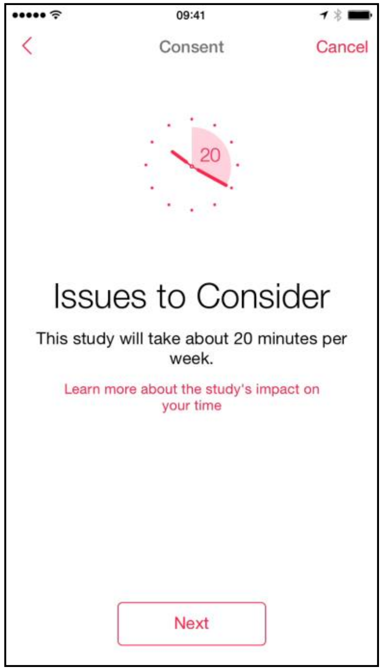
Learn more about how data is used

Protecting Your Data

Your study data will be encrypted on the phone and stored, without your name, on a secure cloud server.

Learn more about data protection

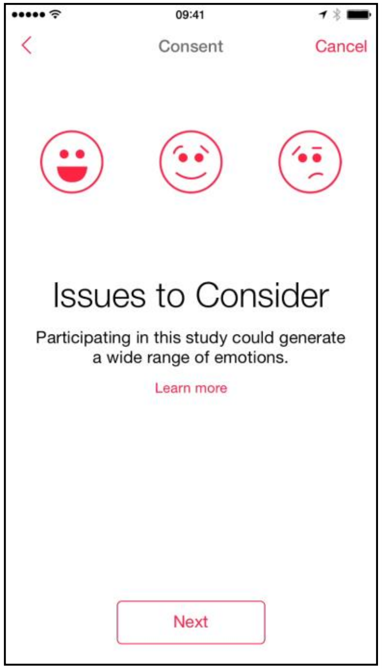
Impact on your life & Issues to consider



Issues to Consider

This study will take about 20 minutes per week.

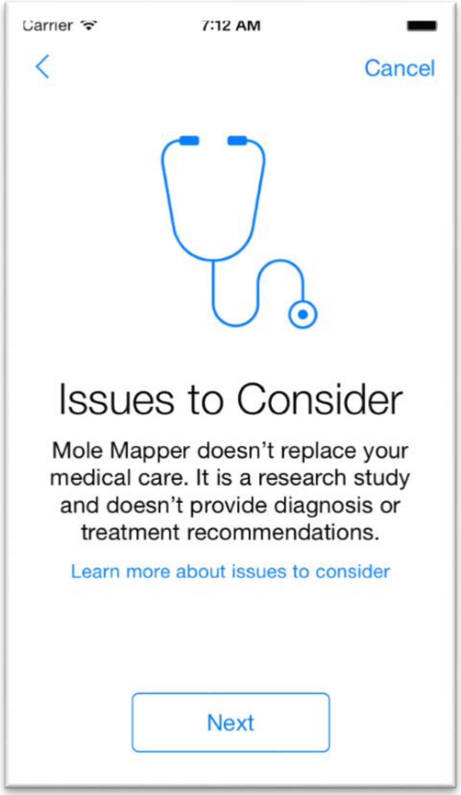
Learn more about the study's impact on your time



Issues to Consider

Participating in this study could generate a wide range of emotions.

Learn more



Issues to Consider

Mole Mapper doesn't replace your medical care. It is a research study and doesn't provide diagnosis or treatment recommendations.

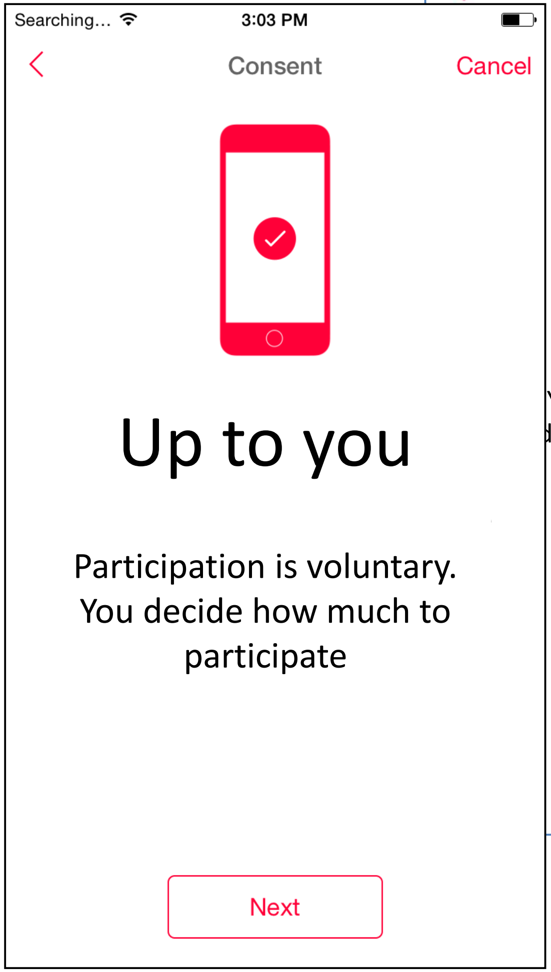
Learn more about issues to consider

Issues to consider

Your DNA is similar to the DNA of your biological relatives.

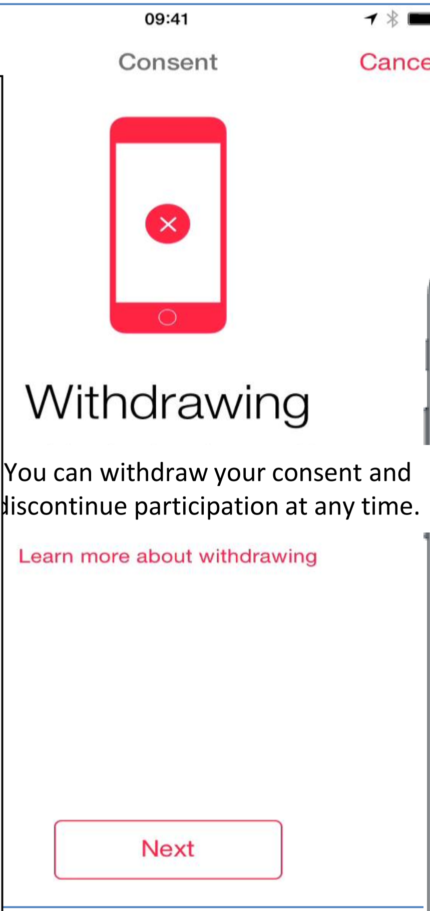
learn more

Free will



Up to you

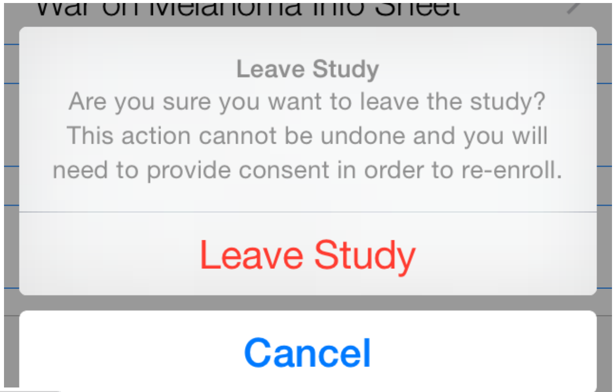
Participation is voluntary. You decide how much to participate



Withdrawing

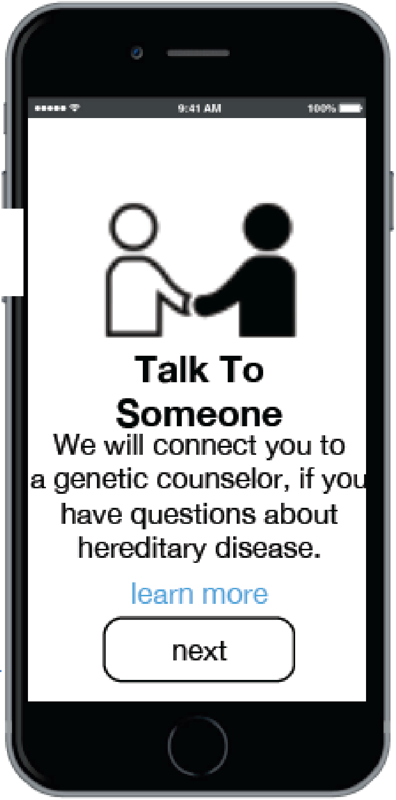
You can withdraw your consent and discontinue participation at any time.

Learn more about withdrawing



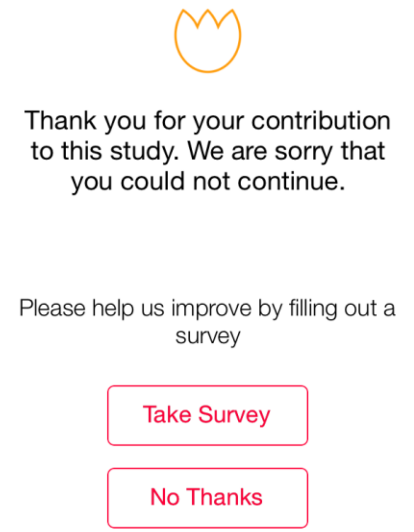
Leave Study

Are you sure you want to leave the study? This action cannot be undone and you will need to provide consent in order to re-enroll.



Talk To Someone

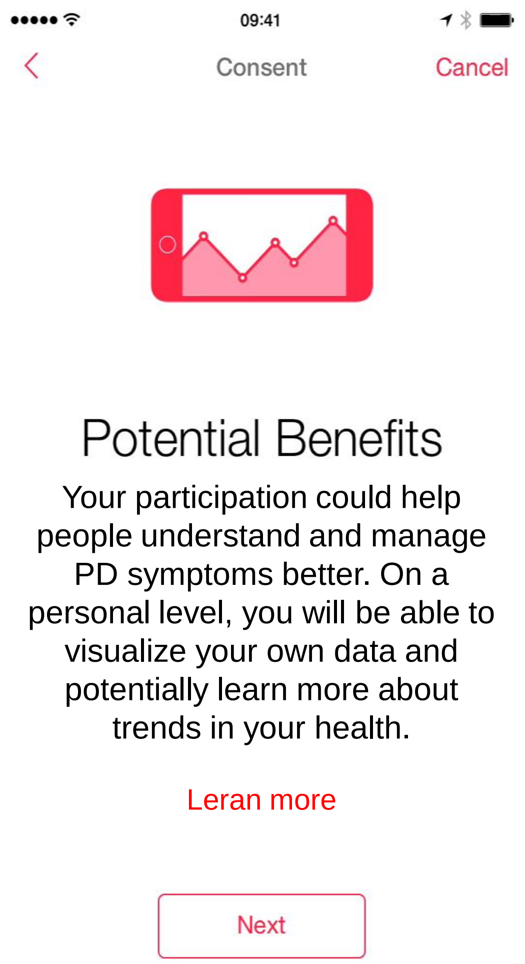
We will connect you to a genetic counselor, if you have questions about hereditary disease.



Thank you for your contribution to this study. We are sorry that you could not continue.

Please help us improve by filling out a survey

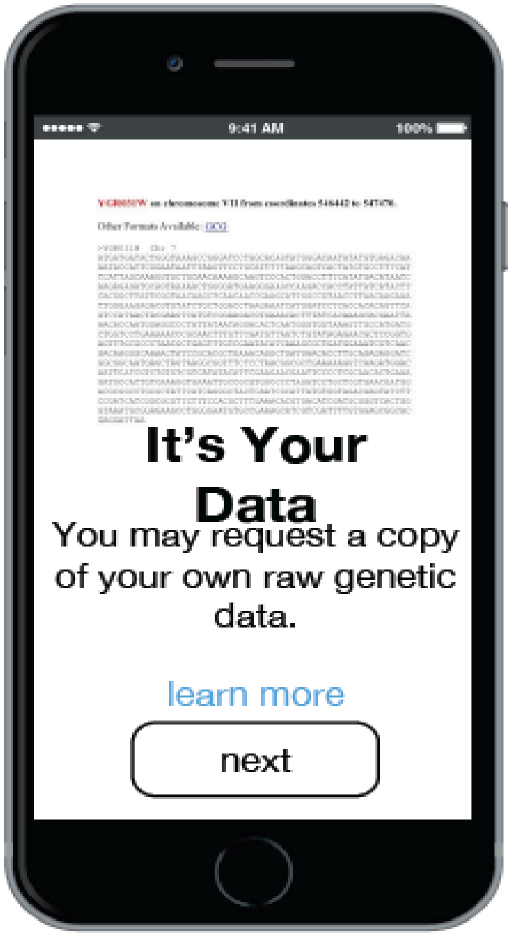
Potential benefits



Potential Benefits

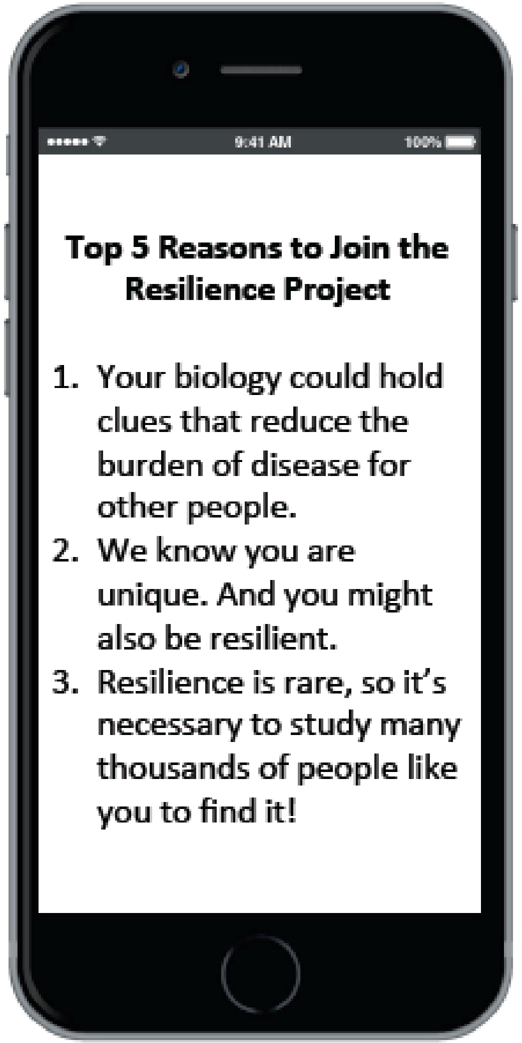
Your participation could help people understand and manage PD symptoms better. On a personal level, you will be able to visualize your own data and potentially learn more about trends in your health.

Leran more



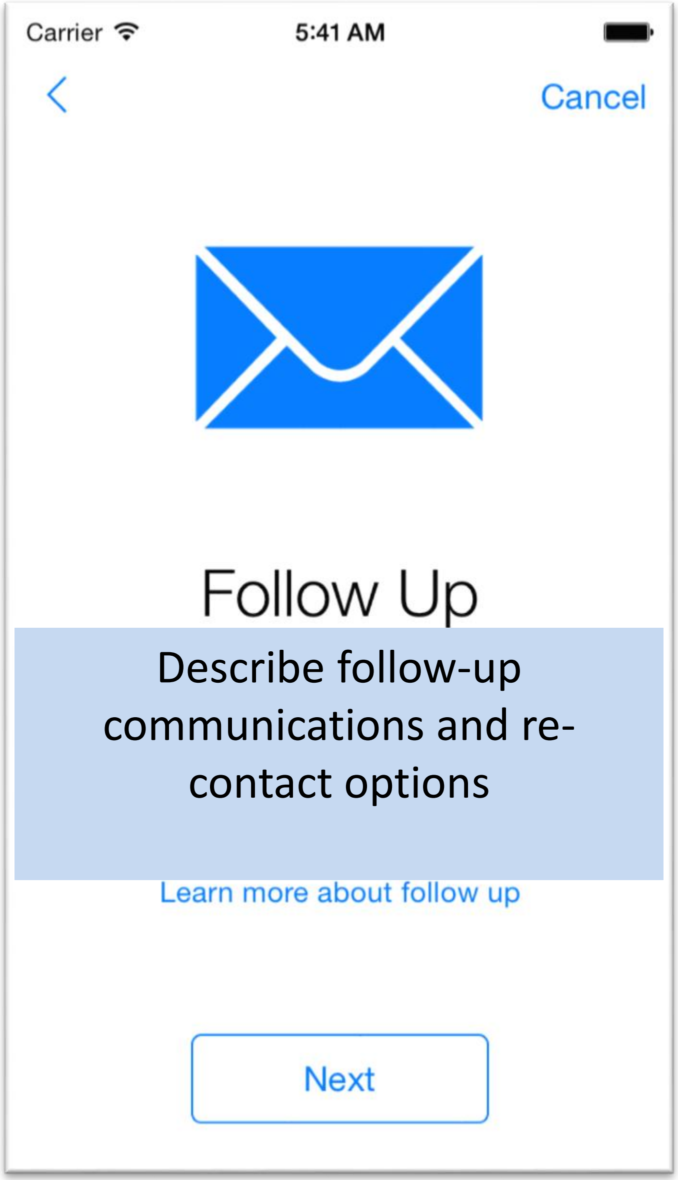
It's Your Data

You may request a copy of your own raw genetic data.



Top 5 Reasons to Join the Resilience Project

1. Your biology could hold clues that reduce the burden of disease for other people.
2. We know you are unique. And you might also be resilient.
3. Resilience is rare, so it's necessary to study many thousands of people like you to find it!



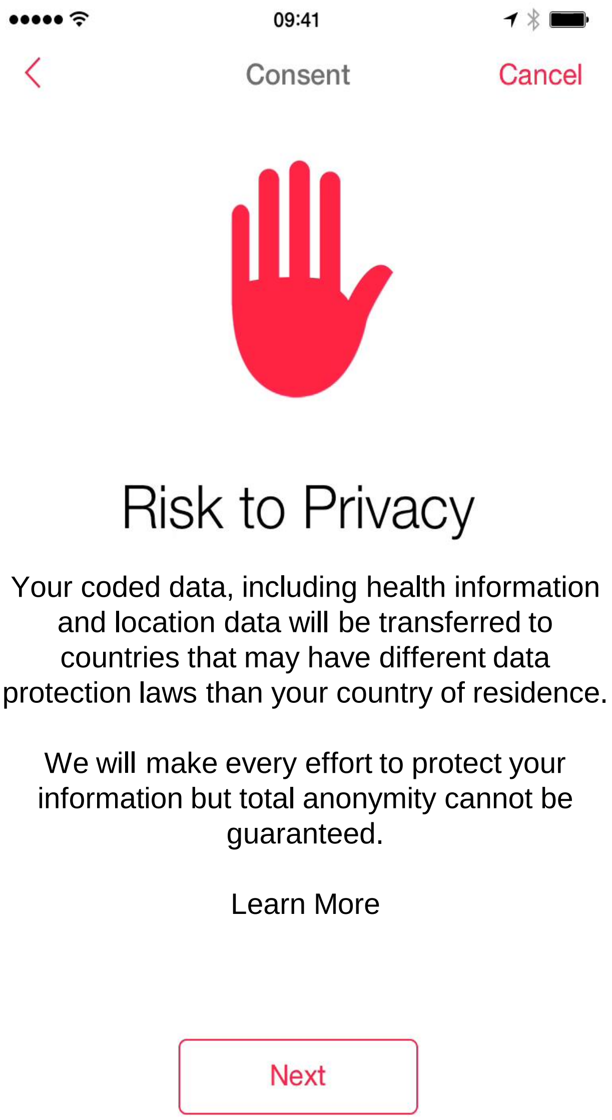
Follow Up

Describe follow-up communications and re-contact options

You may be invited to participate in additional activities or “modules” of the project. Each module has its own eligibility requirement. Your participation in these modules is optional. When there is a study activity or module we’d like you to consider we will contact you. We can choose various communication options.

If you have questions, please contact <study contacts>

Main risk highlighted prominently



Risk to Privacy

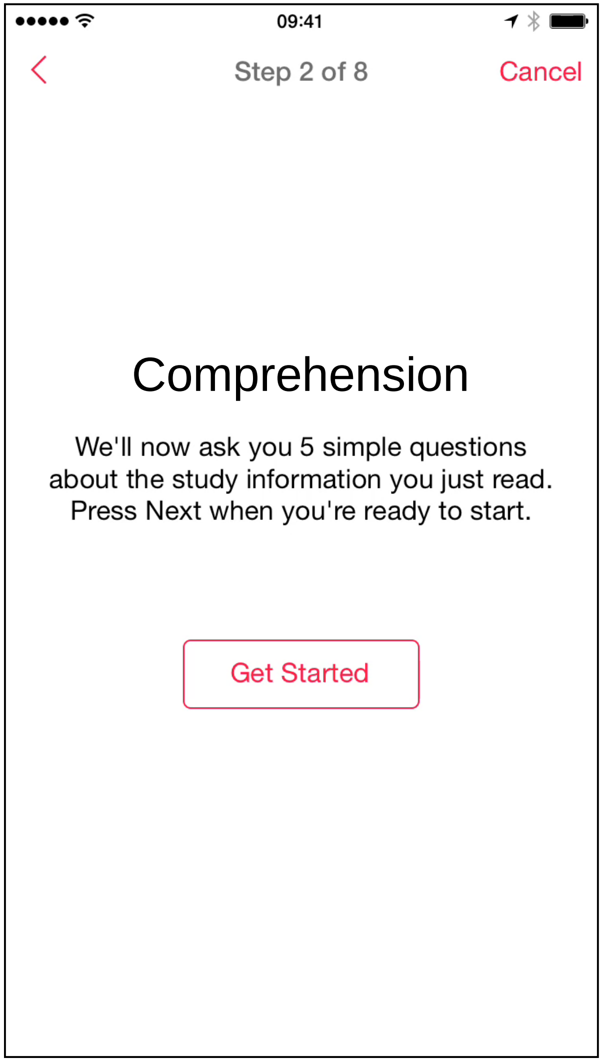
Your coded data, including health information and location data will be transferred to countries that may have different data protection laws than your country of residence.

We will make every effort to protect your information but total anonymity cannot be guaranteed.

Consider the risks.

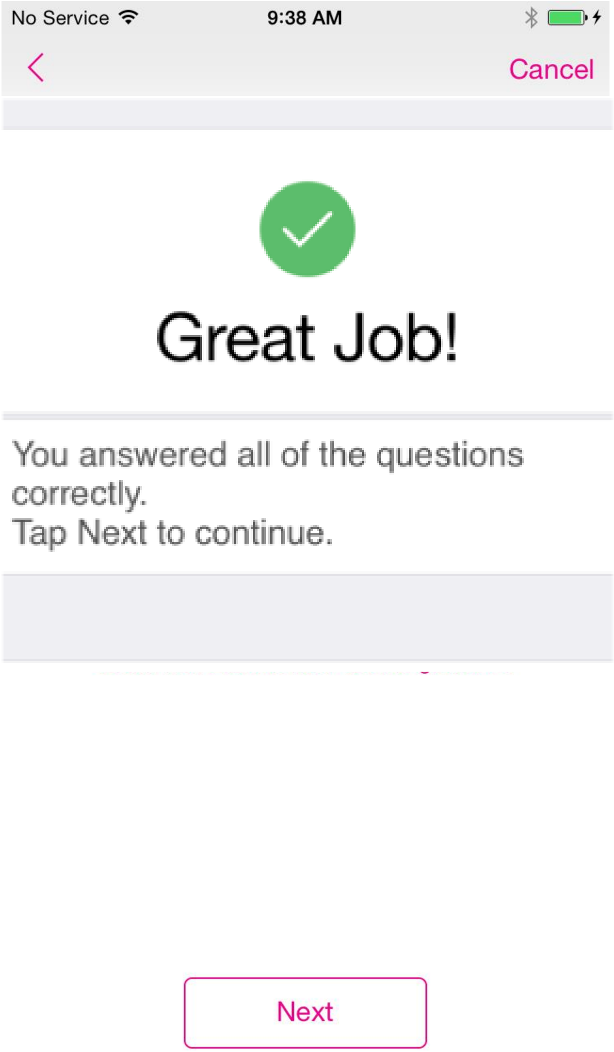
Take the time you need to think it over

Comprehension assessment



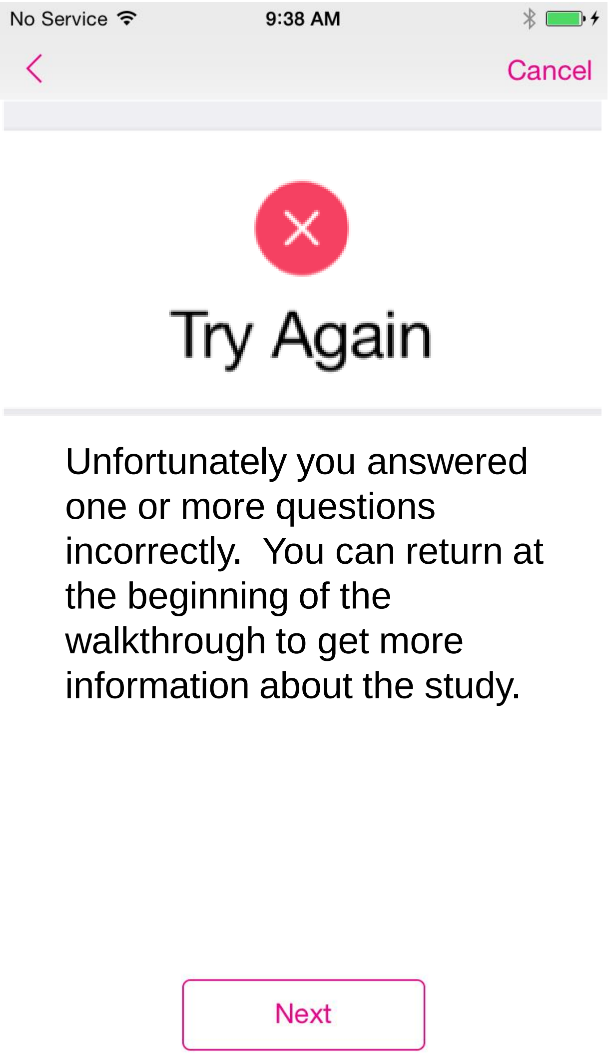
Comprehension

We'll now ask you 5 simple questions about the study information you just read. Press Next when you're ready to start.



Great Job!

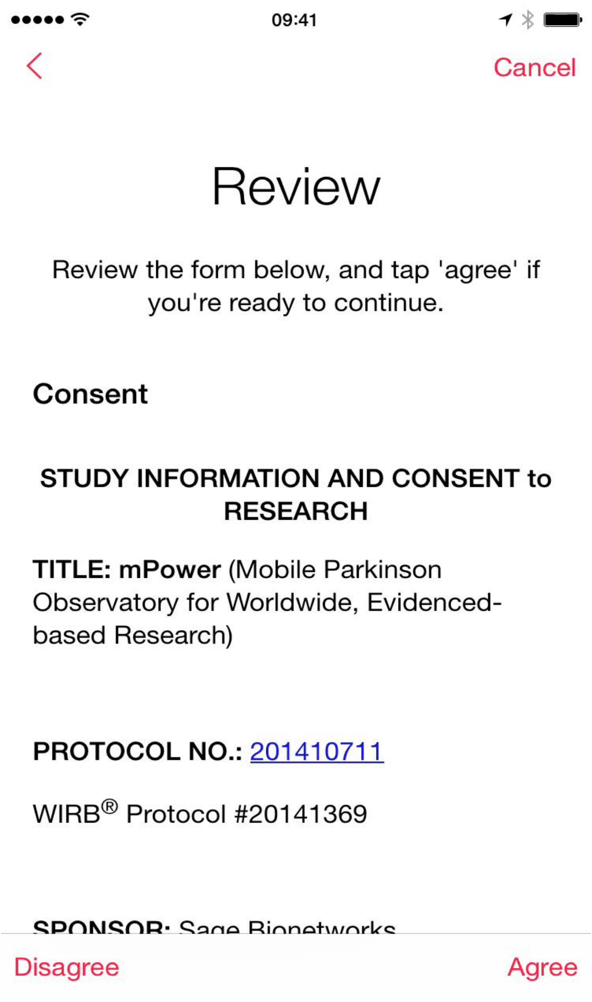
You answered all of the questions correctly.
Tap Next to continue.



Try Again

Unfortunately you answered one or more questions incorrectly. You can return at the beginning of the walkthrough to get more information about the study.

Review Traditional Consent Form



Review

Review the form below, and tap 'agree' if you're ready to continue.

Consent

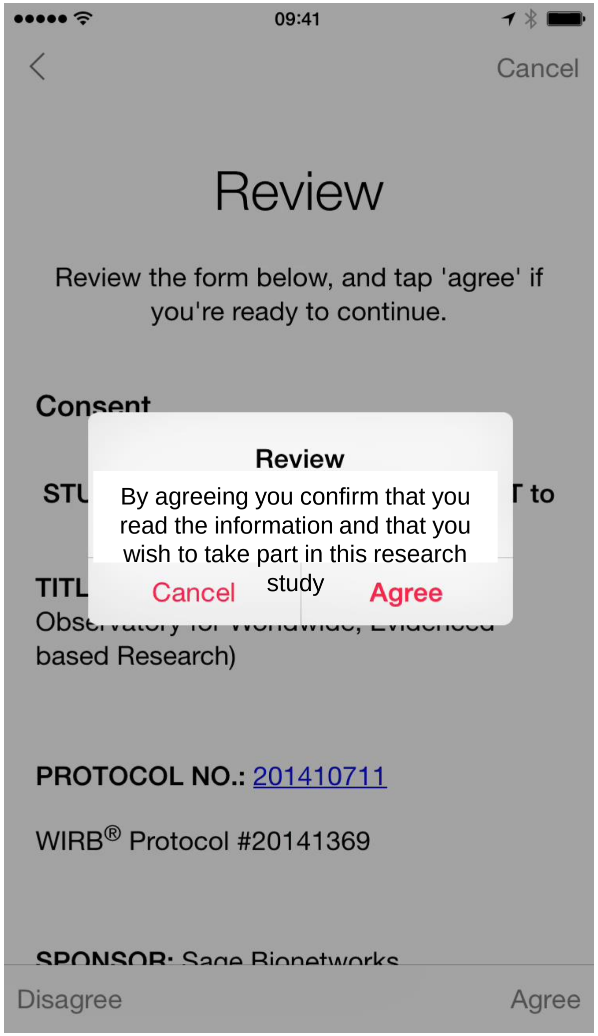
STUDY INFORMATION AND CONSENT to RESEARCH

TITLE: mPower (Mobile Parkinson Observatory for Worldwide, Evidenced-based Research)

PROTOCOL NO.: 201410711

WIRB® Protocol #20141369

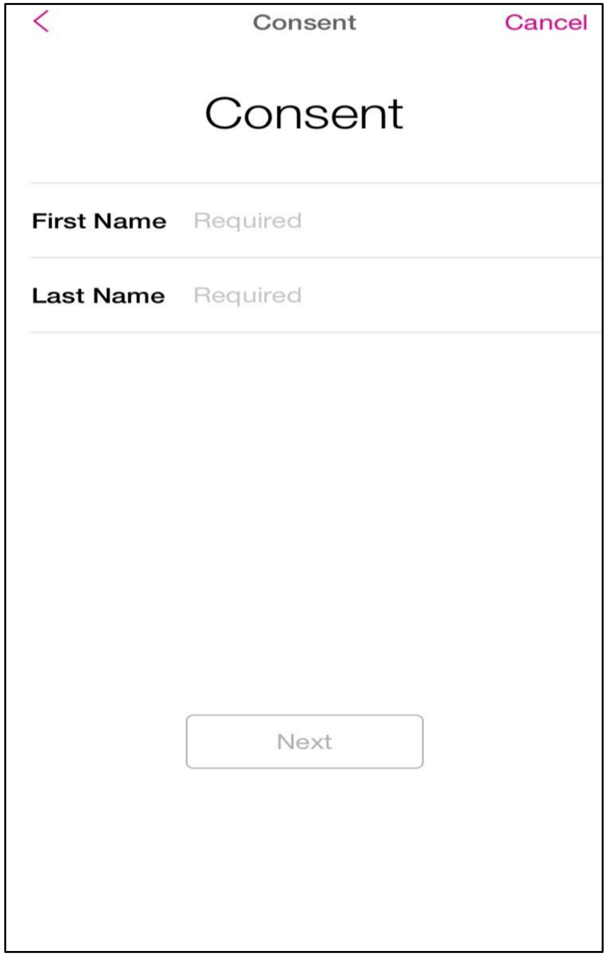
SPONSOR: Sage Bionetworks



Review

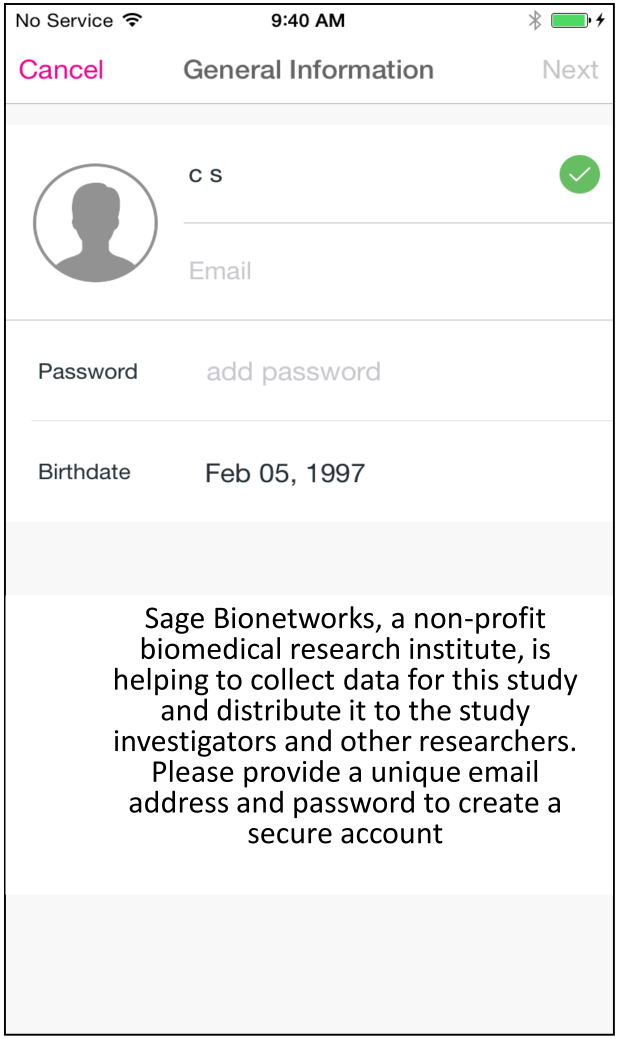
By agreeing you confirm that you read the information and that you wish to take part in this research study

Unambiguous Consent



Please sign using your finger on the line below.

Registration



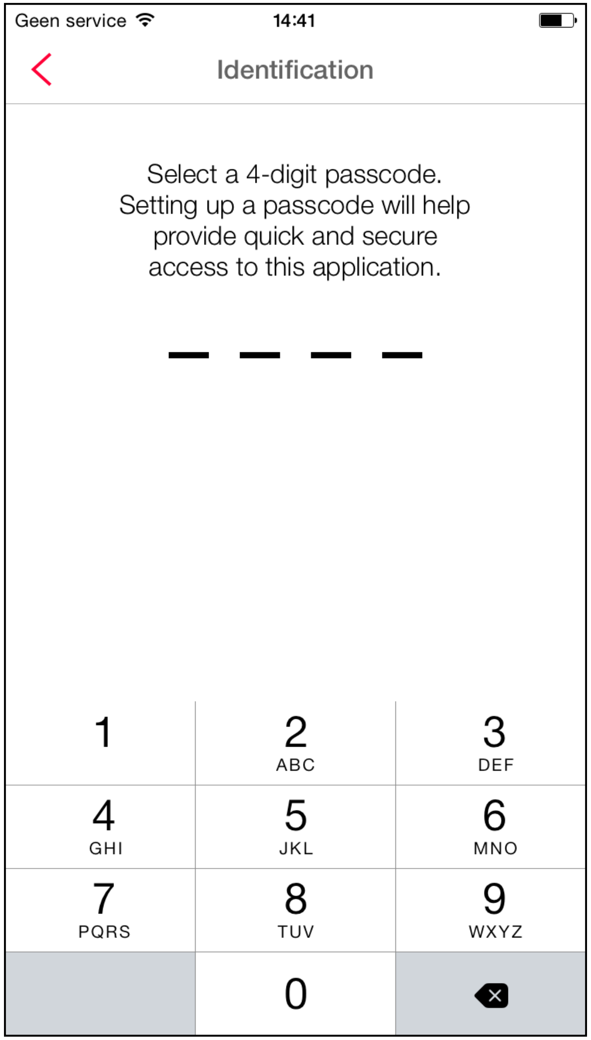
c s

Email

Password: add password

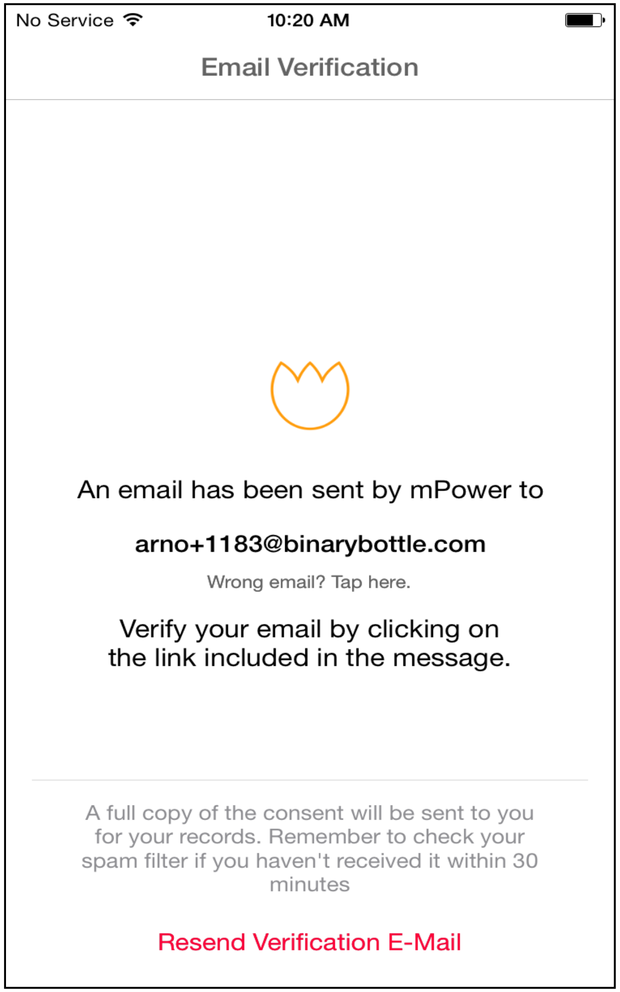
Birthdate: Feb 05, 1997

Sage Bionetworks, a non-profit biomedical research institute, is helping to collect data for this study and distribute it to the study investigators and other researchers. Please provide a unique email address and password to create a secure account



Select a 4-digit passcode. Setting up a passcode will help provide quick and secure access to this application.

Confirmation



Email Verification

An email has been sent by mPower to

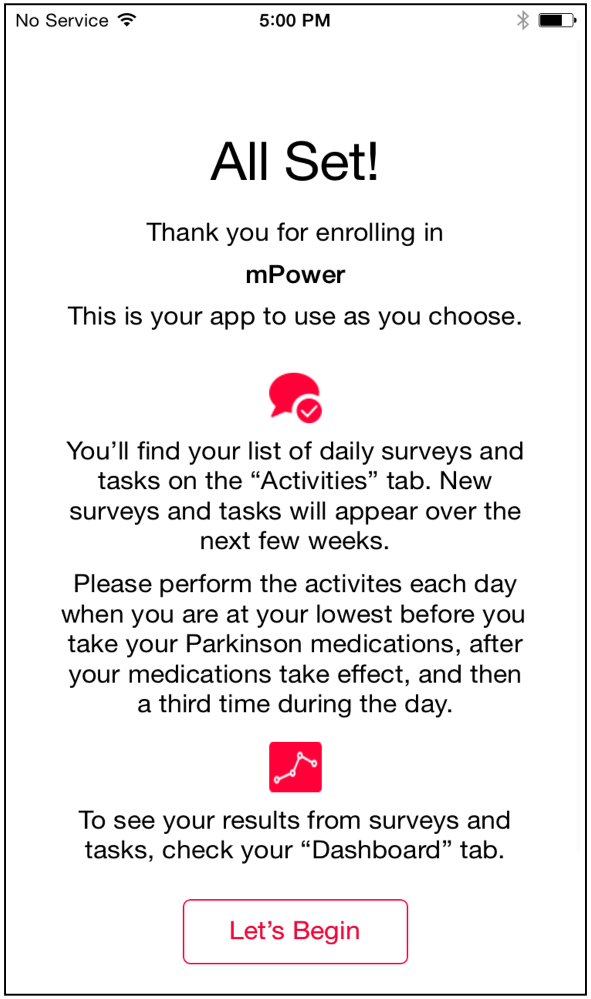
arno+1183@binarybottle.com

Wrong email? Tap here.

Verify your email by clicking on the link included in the message.

A full copy of the consent will be sent to you for your records. Remember to check your spam filter if you haven't received it within 30 minutes

Time to think it over



All Set!

Thank you for enrolling in

mPower

This is your app to use as you choose.

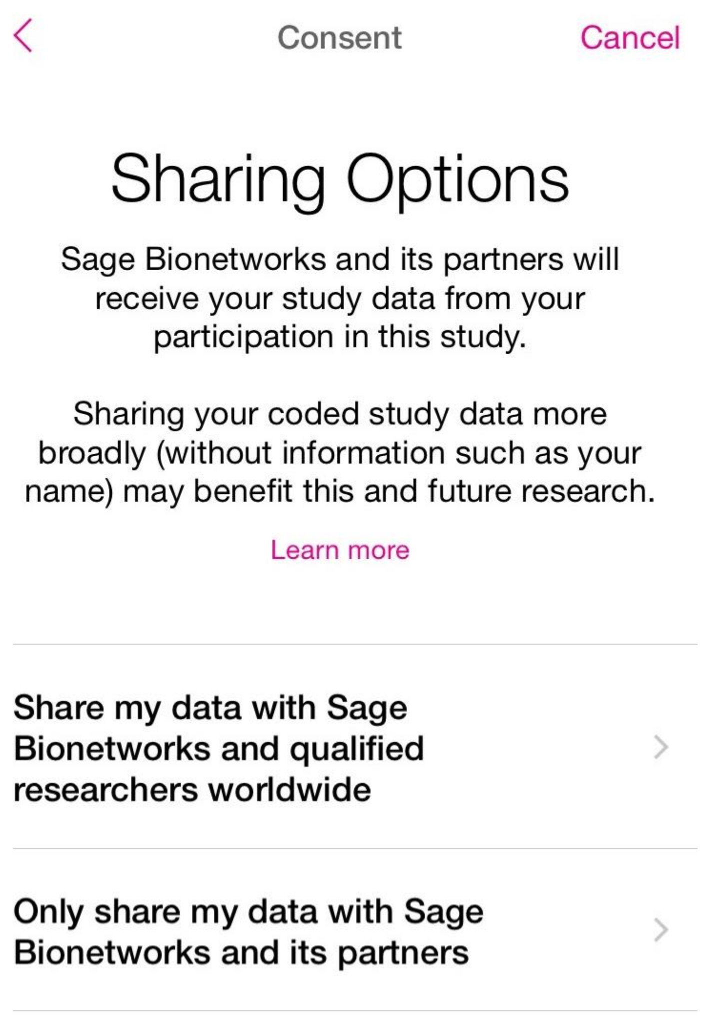
You'll find your list of daily surveys and tasks on the "Activities" tab. New surveys and tasks will appear over the next few weeks.

Please perform the activites each day when you are at your lowest before you take your Parkinson medications, after your medications take effect, and then a third time during the day.

To see your results from surveys and tasks, check your "Dashboard" tab.

75,000 enrolled since 9 March

(across first 5 study apps using the method)



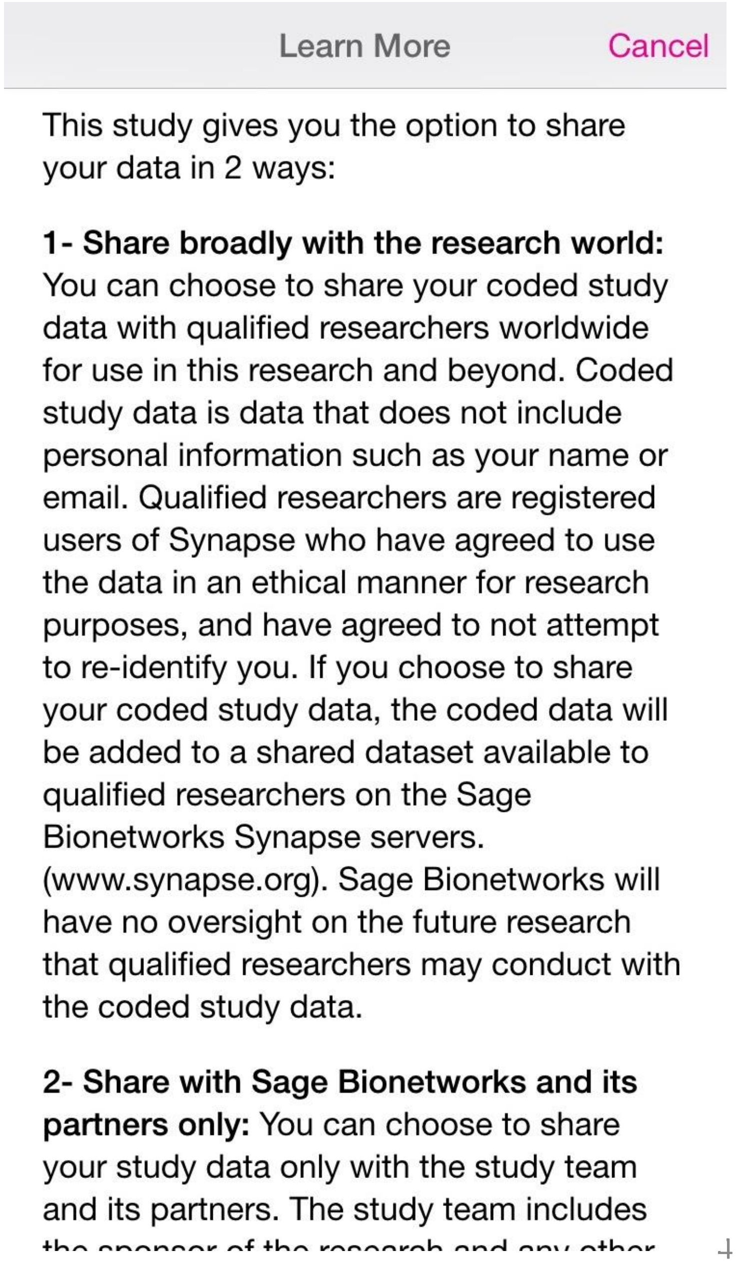
Sharing Options

Sage Bionetworks and its partners will receive your study data from your participation in this study.

Sharing your coded study data more broadly (without information such as your name) may benefit this and future research.

Share my data with Sage Bionetworks and qualified researchers worldwide

Only share my data with Sage Bionetworks and its partners



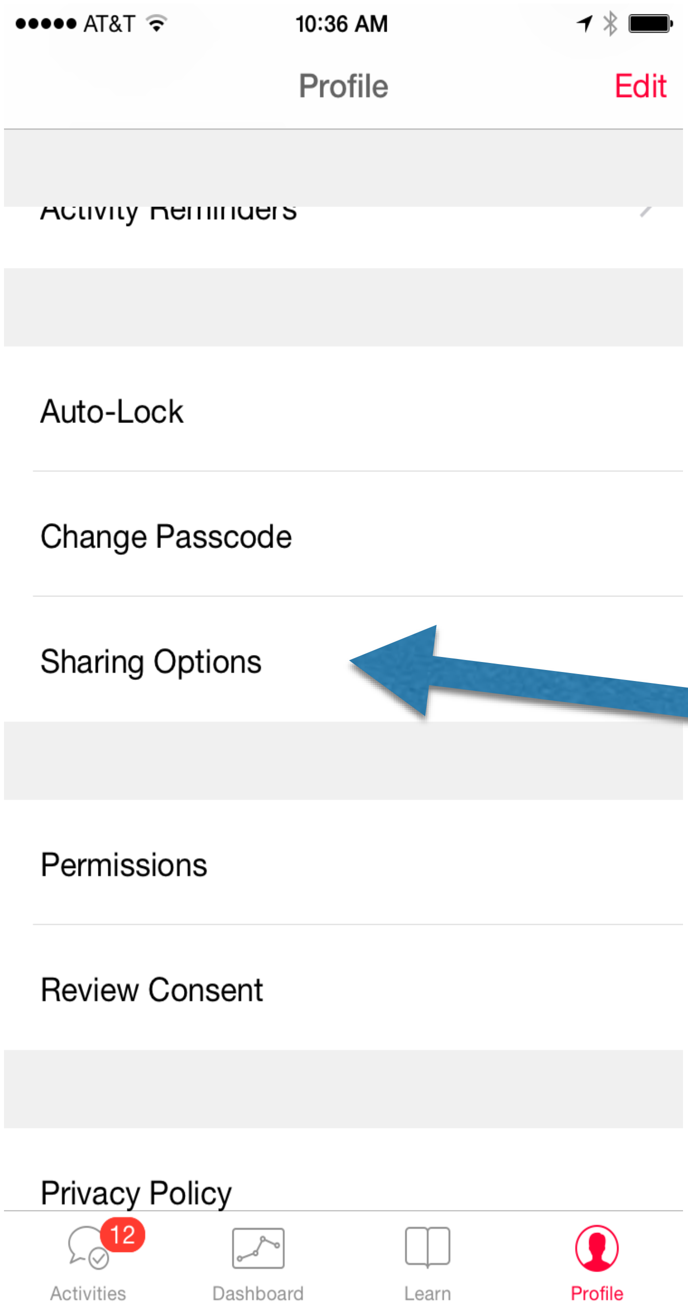
This study gives you the option to share your data in 2 ways:

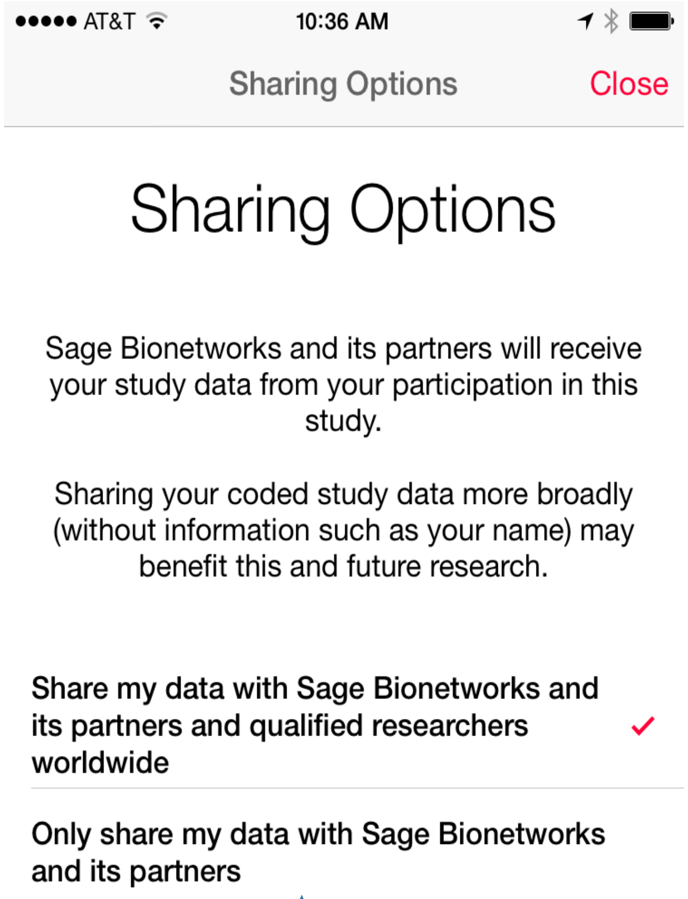
1- Share broadly with the research world: You can choose to share your coded study data with qualified researchers worldwide for use in this research and beyond. Coded study data is data that does not include personal information such as your name or email. Qualified researchers are registered users of Synapse who have agreed to use the data in an ethical manner for research purposes, and have agreed to not attempt to re-identify you. If you choose to share your coded study data, the coded data will be added to a shared dataset available to qualified researchers on the Sage Bionetworks Synapse servers. (www.synapse.org). Sage Bionetworks will have no oversight on the future research that qualified researchers may conduct with the coded study data.

2- Share with Sage Bionetworks and its partners only: You can choose to share your study data only with the study team and its partners. The study team includes the sponsor of the research and any other

Navigating different options for sharing: points to consider

- **What exactly is being shared?**
- **What purpose or purposes are being served by sharing?**
- **Who “owns” the data? Can it be sold?**
- **Who is responsible for the security and privacy of the data?**
- **Who holds the key?**
- **Where will the data be warehoused?**
- **Who will have access to the data?**
- **What happens if I change my mind?**
- **How am I protected if my data is disclosed**?





Sharing Options

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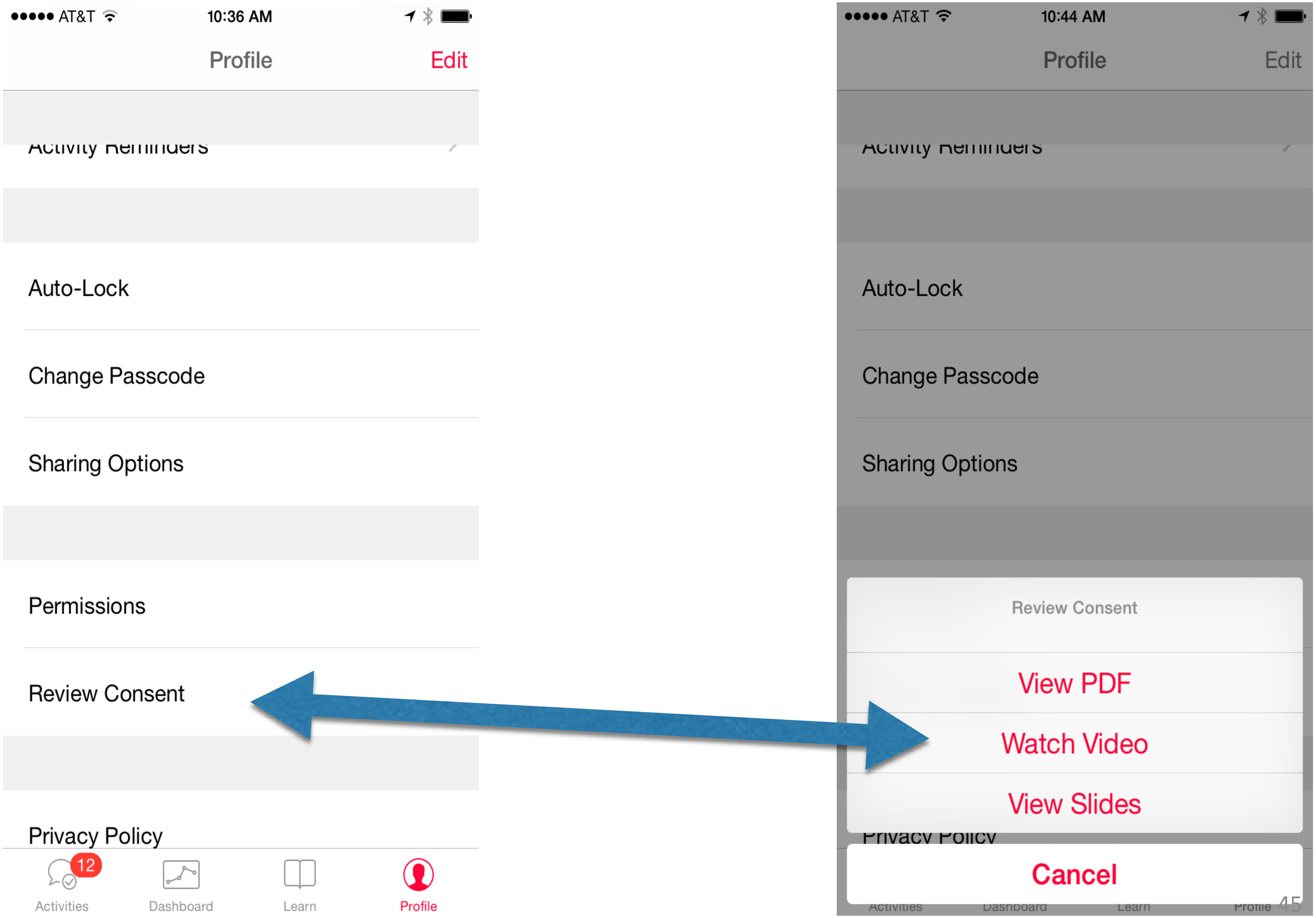
Sharing your coded study data more broadly (without information such as your name) may benefit this and future research.

Share my data with Sage Bionetworks and its partners and qualified researchers worldwide ✓

Only share my data with Sage Bionetworks and its partners

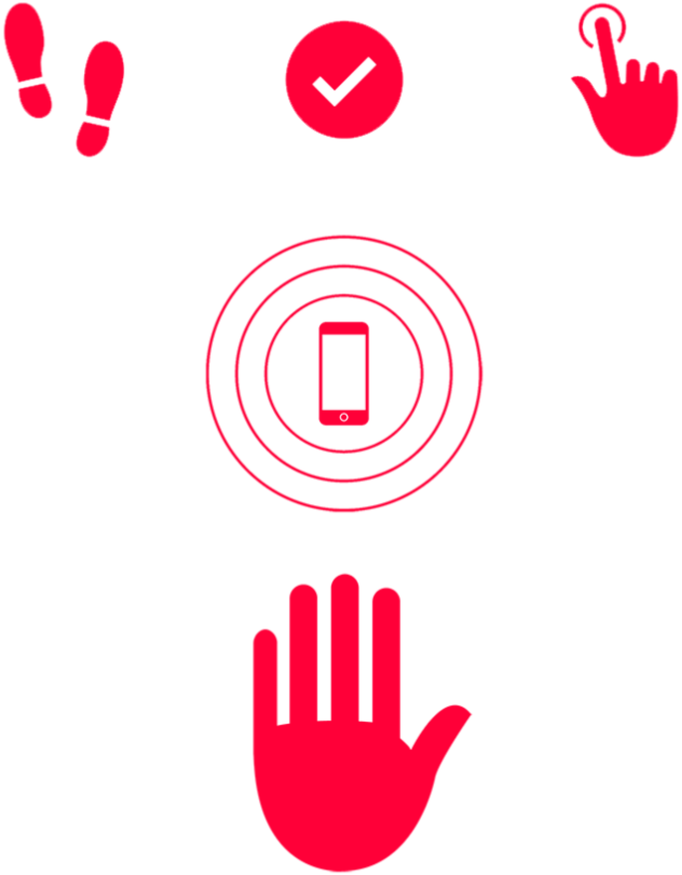
changeable by participant

>70% choose to “share broadly”



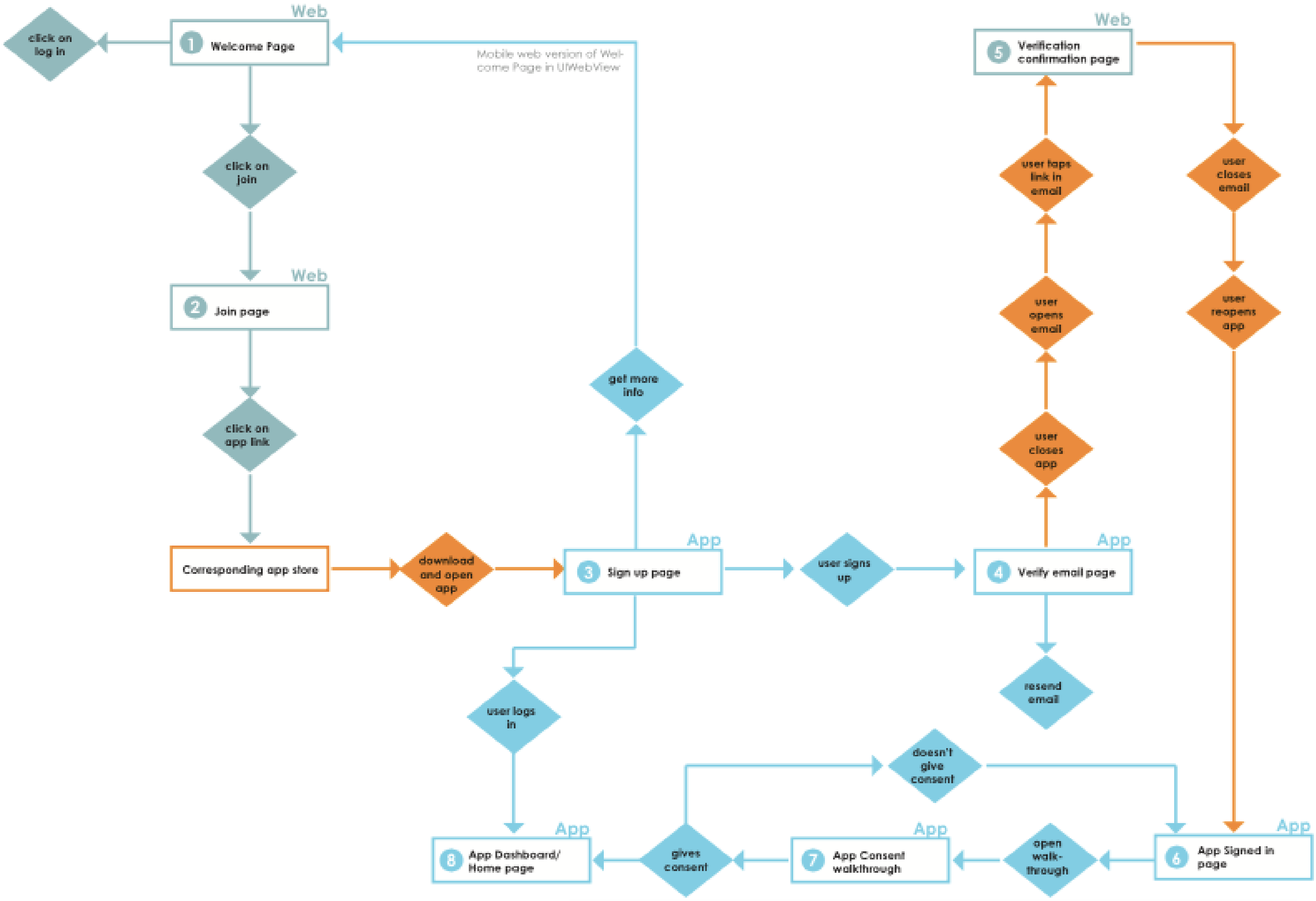
participant-centered consent

open source toolkit



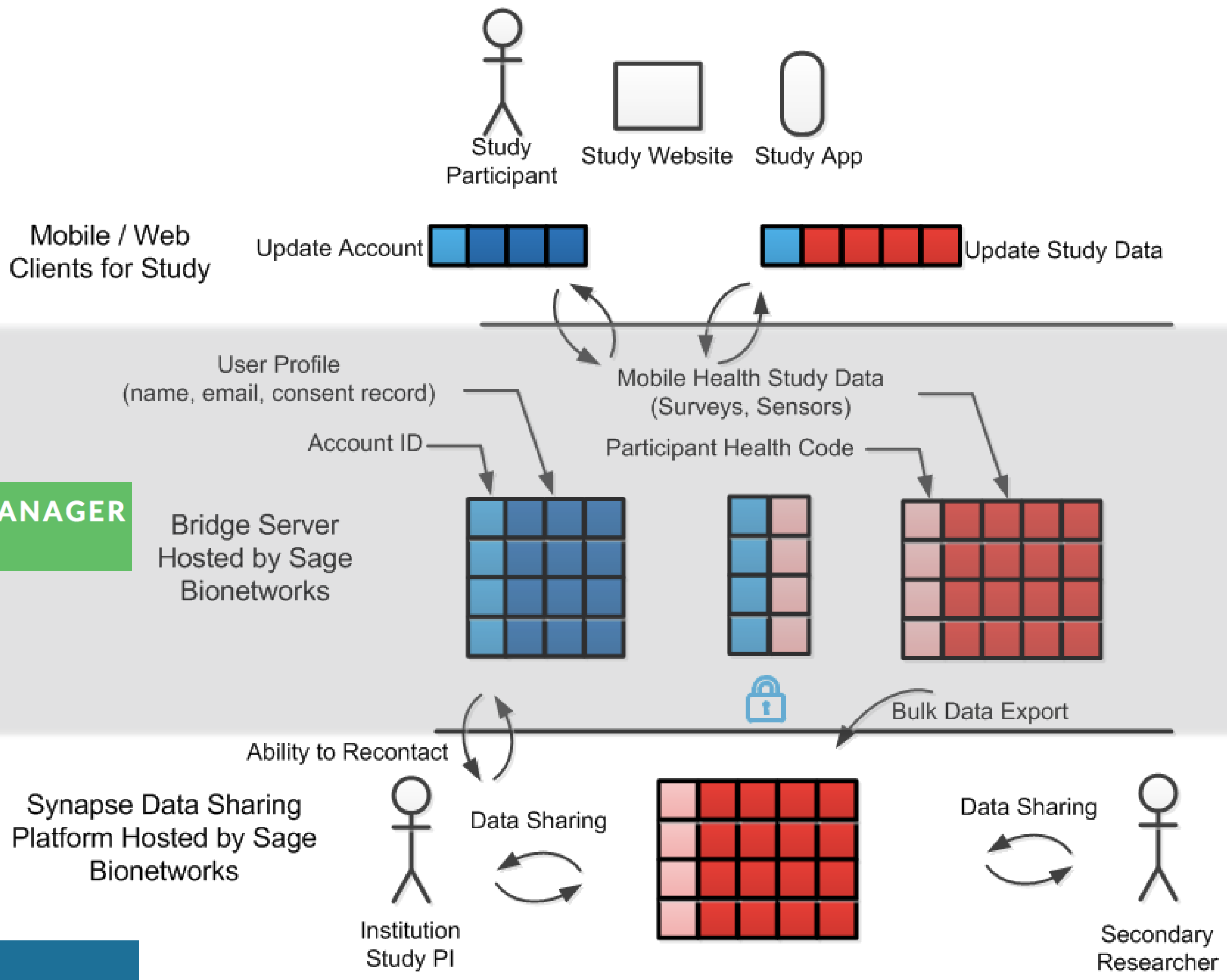
http://sagebase.org/pcc

workflows


Web
click on log in
1 Welcome Page
Mobile web version of Welcome Page in UIWebView
click on join
Web
2 Join page
click on app link
Corresponding app store
download and open app
App
3 Sign up page
get more info
user signs up
App
4 Verify email page
resend email
Web
5 Verification confirmation page
user taps link in email
user opens email
user closes app
user closes email
user reopens app
user logs in
doesn't give consent
App
8 App Dashboard/ Home page
gives consent
App
7 App Consent walkthrough
open walk-through
App
6 App Signed in page

moving beyond the app

participant centered consent



Study Participant

Study Website

Study App

Mobile / Web Clients for Study

Update Account

Update Study Data

User Profile (name, email, consent record)

Mobile Health Study Data (Surveys, Sensors)

Account ID

Participant Health Code

BRIDGE STUDY MANAGER
mPower [staging]

Bridge Server Hosted by Sage Bionetworks

Bulk Data Export

Ability to Recontact

Synapse Data Sharing Platform Hosted by Sage Bionetworks

Data Sharing

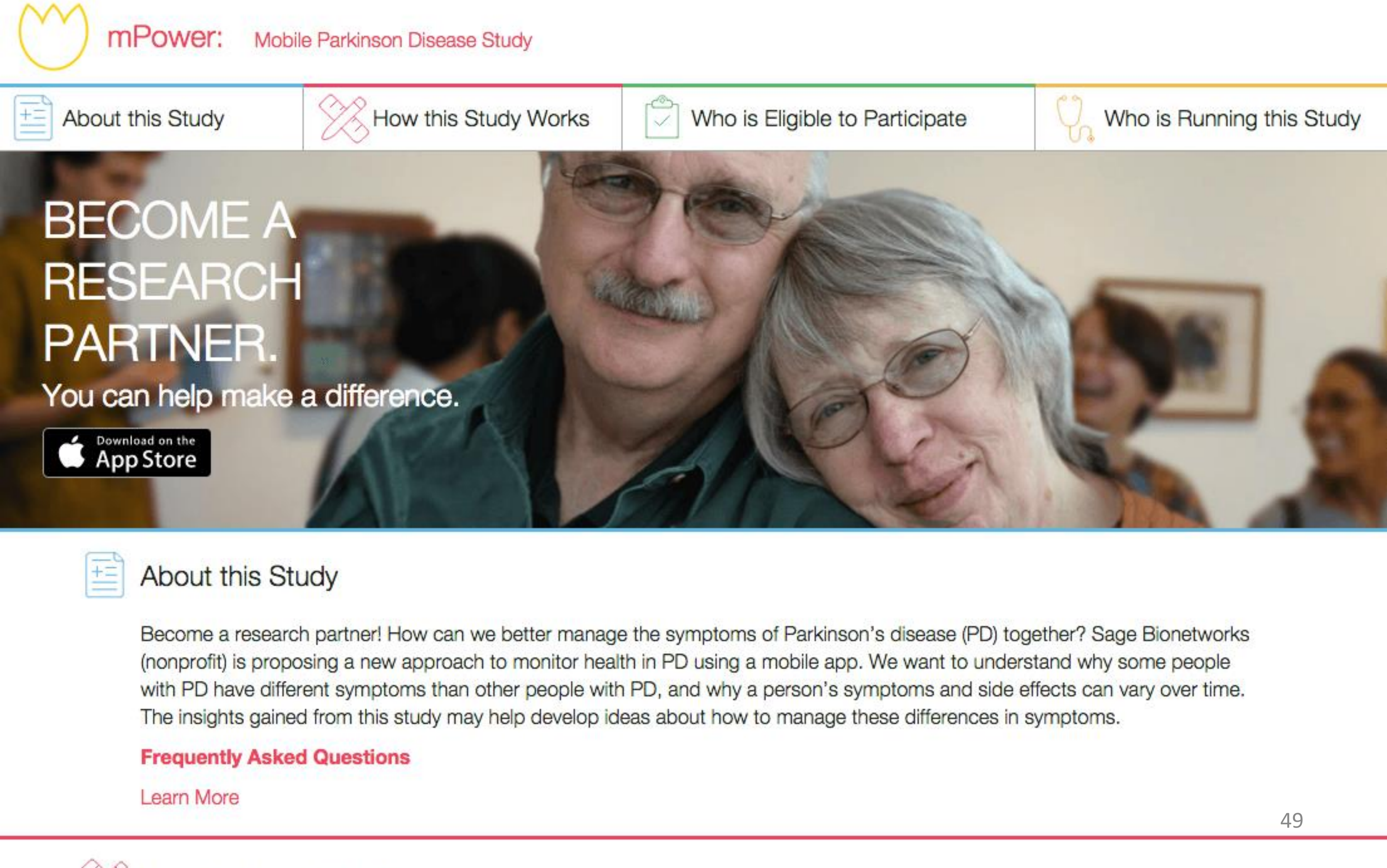
Institution Study PI

Data Sharing

Secondary Researcher

Synapse

web templates and assets



mPower: Mobile Parkinson Disease Study

BECOME A RESEARCH PARTNER.

You can help make a difference.

About this Study

Become a research partner! How can we better manage the symptoms of Parkinson's disease (PD) together? Sage Bionetworks (nonprofit) is proposing a new approach to monitor health in PD using a mobile app. We want to understand why some people with PD have different symptoms than other people with PD, and why a person's symptoms and side effects can vary over time. The insights gained from this study may help develop ideas about how to manage these differences in symptoms.

Frequently Asked Questions

Learn More

Thank you

Sage
BIONETWORKS

Christine Suver
christine.suver@sagebase.org