IRB Review of mHealth Research: Best Practices and Future Challenges

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1:00-2:30 PM ET

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Webinar Objectives

- A look at the landscape of mHealth research review; what’s been accomplished and a glimpse into the future
- Discuss the complexities of informed consent in mobile apps and innovation that is occurring
- Highlights of special nuances related to mHealth study designs, risks, data security, confidentiality, and privacy
- Best practices & advice on IRB review of mHealth research studies

PCC Toolkit

How it works
Outline

- Identify clinical concepts
- Create “Minimum Viable Interface”
- Create Assessment and Sharing options
- Open source assets

Example: Parkinson mPower Study

IDENTIFY CLINICAL CONCEPTS
1. **Tiered information access** by participants
2. “**Pictorial**” dominant on first information tier
3. **Text dominant** on second information tier
4. Require **perfect score** on short assessment
Screens are organized in consistent areas

- **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.

Learn More
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.
Integrate study-specific concepts with study-generic concepts

Welcome
The Research
Your Data
Impact on your life - issues

What is involved
Your Rights
Potential Risks and Benefits
Comprehension - Review and Consent

Example: Parkinson mPower Study
MINIMUM VAILABLE INTERFACE

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1. Series of interviews and requirements gathering

2. Interaction design process and prototyping

3. Consent development

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

You have the option to contribute activity data collected through:

- The sensors on your iPhone or any wearable activity device (like a Fitbit or Jawbone)
- Other applications and data available through Healthkit.

You can choose not to provide this data and still participate in the study.

We will NOT access your personal contacts, other applications, personal photos, text or email messages.
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

Protecting your Data
We will replace your name with a random code. The coded data will be encrypted and stored on a secure Cloud server under the control of Sage Bionetworks to prevent improper access.
Learn more about how your privacy and identity are protected

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.

We will use a random code instead of your name on all your study data. This code cannot be used to re-identify you.

The Data will be encrypted and stored on a secure Cloud server under the control of Sage Bionetworks to prevent improper access.
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

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

Learn more about withdrawing

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. If you withdraw from the study, we will stop collecting new data. The coded study data that you have already provided, and that have already been distributed, will not be able to be destroyed or deleted.

To withdraw from this study please contact the Dr. Andrew Trister by email PDApp@sagebase.org or call +1-208-667-2103 or click on the withdraw link in the profile page of the application.
Issues to Consider

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

Learn more

Risk to Privacy

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

Learn more

Participating in this study may change how you feel. You may feel tired, sad, energized or happy.

Participation in this study may involve risks that are not known at this time. You will be told about any new information that might change your decision to be in this study.

We take great care to protect your information, however there is a slight risk of loss of privacy. This is a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research study data to respect your privacy. However, even with removal of this information, experts in re-identification may be able to reverse our processes and/or attempt to re-identify an individual given enough cross-reference information about him or her.

Accidental public disclosure may occur due to unintended data breaches including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.
CREATE ASSESSMENT AND SHARING OPTIONS

Example: Parkinson mPower Study

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.
What is the purpose of this study?

Understand the fluctuations of Parkinson's disease symptoms

Treating Parkinson's disease

My name will be stored with my Study data

Yes

No

Many researchers will be able to access my study data

Yes

No

I will be able to skip any survey question

Yes

No
I will be able to stop participating at any time

Yes

No

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
WIRE® Protocol #20141369

Disagree Agree
Unambiguous Consent

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.

Registration
Confirmation

Time to think it over

An email has been sent by mPower to an@116385binarybottle.com. 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 file if you haven’t received it within 30 minutes.

Resend Verification E-Mail

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 activities 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.

Let’s Begin

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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 its partners and qualified researchers worldwide

Only share my data with Sage Bionetworks and its partners

changeable by participant
OPEN SOURCE ASSETS

“Participant-Centric Consent Toolkit”

http://sagebase.org/pcc
Open Source Methods

Iconographic representations of key concepts in informed consent

Attribution or public domain

Design Layouts

The pages are organized in 6 distinct areas:
Workflows

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? Saga Biometrics (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
Issues in Developing Digital & Mobile Research Apps

- How do you conduct consent entirely remotely?
- How does remote consent differ from traditional consent?
- How does mobile health research impact recruitment?
- How can privacy be protected in research using mobile phones?
- What type of research can you do with an app within current regulatory boundaries?
- What is a minimal risk vs. greater than minimal risk digital & mobile health study?

Novel vs. Better vs. Unfamiliar

Unfamiliarity: As we’ve seen, mobile health research has been going on for a few years. Most IRBs are simply unfamiliar with it because they haven’t seen it yet.

Better Technology: Depending on what the study is, a portion of mobile health research is simply doing the sorts of research we’ve seen before, but now using better technology. Once we filled out surveys using pen & paper, then Scantron, then computer, then mobile device.

Novel Technology: A useful combination, truly new method for collecting data, new data type, or emergent property. Examples include continuous monitoring, GPS tracking and integrations, some forms of telemedicine, etc.
Belmont… again

- Autonomy: eConsent
  - Tech can help us do this better: will it work, or will it backfire?
  - Multi-modal consenting.

- Risk: Benefit & Risk determination
  - New or Different risks: Ethics of telemedicine and whether you’re providing medical care = who is responsible?
  - Magnitude of Risks: Are some of the risks, which historically are considered minimal now greater than minimal? (confidentiality, privacy, cybersecurity)

- Justice considerations:
  - Access to research gets blown apart, in a good way
  - Local context could be completely lost
  - What about those who can’t afford it?
  - Is it platform-specific?

Digital & Mobile Health Related Risks

Privacy / confidentiality (GPS data, IP addresses, location-based services). Much of this is directly tied to the technology itself.

Collecting information from or about bystanders. What data types or activities are more likely to have this occur?

Consent legitimacy: can you verify the person using it is the person you think they are and is appropriate to be in the study? What technical solutions can accomplish this verification, and do you need it?
Mobile Health Related Risks

Participants may be self-conscious about giving constant information.

Participants may modify their behavior because they know they are being observed in some way (Hawthorne Effect)... in some cases, this is the point!

Participants might become so accustomed to being monitored/giving information that they forget about, resulting in giving information they wouldn’t otherwise want to share. (anti-Hawthorne Effect)

Mobile Health Related Risks

Mandating certain information in order to participate;
• What is coercive?
• What is undue influence?
• What is a data grab?

The scope of WHO could enroll will really matter. Not just the characteristics of the individual, but the situation that they may find themselves in matters too.
Silicon Valley vs. Healthcare

Tech industry professionals go about their work in a fundamentally different way than human subject researchers who submit their work to IRBs.

The two cultures need to court one another a little more and spend the time to learn where the boundaries are.

Difficulties of interdisciplinary work!
Read more about how to tackle that here…
http://www.interdisciplinarystudiespcz.org/

This is not a new problem!

EULAS vs. Consents

- Consent is a process, not a click-box
- The End User Licensing Agreement (EULA) used in most of the tech industry is the long legalistic language in tiny print that the user simply clicks accept to without usually reading.
  - This got Facebook in a bit of trouble when they included ‘research’ somewhere in there.

Investigators and IRBs need to teach our colleagues in the technology industry about how we view and approach consent.

A focus should be placed on the opportunity to improve the consenting process using technology.
Multi-Modal Consenting

One exciting development in digital and mobile health are going to come out of the consenting process.

**Multi-modal consenting**: using visual (charts, graphics, videos), and written consenting that includes interactivity (quizzes, check-boxes, discussions etc.) in e-consenting platforms.

**The Block Rule**: the use of three different modalities to adequately ensure that subjects understand and comprehend the study is likely enough to meet the regulatory criteria for informed consent.

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**eConsent Example:**

**Asthma Health App & the Asthma Mobile Health Study**

Acknowledgments in the beginning…. Linda Rogers & the rest of the Asthma Mobile Health Study team.
The Asthma Health App
The Asthma Mobile Health Study

- Users use app to learn about asthma and track/manage their asthma
- Collect large volume, real time data on asthma from anywhere in the U.S. outside of an academic research center

The Asthma Health App
The Asthma Mobile Health Study

- Key features/inputs (tasks & surveys):
  - Asthma history
  - Symptom and medicine surveys (daily)
  - Health care utilization (weekly)

*Licensing of standardized questionnaires required*
The Asthma Health App
The Asthma Mobile Health Study

- **Key features/output:**
  - Monitor symptoms and lung function and track graphically (peak flow)
  - Feedback on asthma status based on above criteria
  - Weather and air quality warnings
  - Educational materials

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**eConsent: video**

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Asthma Health App by Mount Sinai:

- Welcome screen
- About the App

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Yvonne Y. Chung, MD, PhD
Assistant Professor of Medicine and Epidemiology
Institute for Genomics and Multiscale Biology
**eConsent: eligibility**

- Age > 18
- Have MD diagnosis of asthma and using asthma medication
- Not pregnant
- Collect data on smoking and comorbid diseases and censor data accordingly in analysis
- Prompt to uninstall app if not eligible

**Iconic interfaces with layered information**
Informed consent discussion vs. assessment of comprehension

- Informed consent discussion with investigator is considered the cornerstone of informed consent
- How to implement this with remote research?
- Test of understanding of main issues highlighted in iconic interfaces
- Can request phone or email contact for questions, verbal discussion

Documenting informed consent

- Electronic copy emailed to participant and investigators
- Consent in app at all times for reference for participant
- Electronic signed consent stored securely at research site
Novel aspects of eConsent

- Multistep process, multimedia (low literacy, numeracy)
- Proceed through process, as interested, at your own pace
- Access to full standard consent document in app at all times during the study
- Objective checking/documenting comprehension in real time
- Corrective feedback during assessment of comprehension aids retention, and increases understanding.
- Technical approaches to ensure potential participant is engaging with the content and not just swiping through
- Have the ability to reaffirm consent!

Redefining Study Design

In a number of cases, the entire digital/mobile health platform is the study design.

- The interactions and interventions in the app
- The underlying schema and build of the app directly impacts design
- Exploratory apps with lots of integrations make the details “under the hood” critical to understand.
IRB Best Practices for mHealth

- Have IT Professionals serving on Boards as consultants or voting members
  - Have your HIPAA and IT Director involved prior to IRB submission.
- Start the dialog early. Ethical & Regulatory review can impact product development!
  - Consider designating someone to become an expert in this in the office.
- Get Legal Involved early & fight the good fight! Look at potential conflicts between EULAs for devices / systems and the eConsent.
- The answer is usually ‘yes, let’s figure out how…’ As a community, we run the risk of paternalistically holding back or delaying research when population may already be doing things like this or more themselves...
  - Fitbit/Fuelband etc.
  - Blood Pressure Monitors, Glucose monitors
  - Asthma inhalers

IRB Best Practices for mHealth

- The Block Rule: Three different methods, at a minimum, for eConsent (charts, graphs, questions, videos, etc.)
- Get tabular and chart form explanations of the app and the who/what/where/when/why/how of the data.
- Get mockups of the app submitted. Once it’s built, it could be expensive to modify.
- Non-compliance will be different: foreign country access, jurisdictional issues, data integrity of false reporting, active undermining of the research by bad actors.
Digital & Mobile Health Data: Graphical & Tabular Explanations

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<td>Under what circumstances or situation will it be entered?</td>
<td>By user action?</td>
<td>Primary data for the study?</td>
<td>Data about the device/platform?</td>
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<td>Survey?</td>
<td>Interaction or usage of device/platform?</td>
<td>By device/platform?</td>
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Prediction: Where could this go

- Apps might not really be the future: multi-platform issues, scalability, usefulness could suffer if it’s too app focused of a world.
- Developers, Researchers, Reviewers need standards: Apple & Google should talk more…
- Apps as devices: It’ll happen; the FDA will regulate this to some extent likely within it’s existing structure. (see also their guidance)
Prediction: Where could this go

- CROs & Sponsors have a huge role to play
  - They’re starting…
- mHealth → EMR | Integration really matters!
- Lots of hype creating a bullish market: who is going to be the Theranos of the mHealth sector?
- Will there be a Henrietta Lacks moment? Perhaps at a population level around Big Data.

Questions and comments

To submit a question, simply click on the Q & A menu at the top of the screen.

webinars@primr.org
Thank you!

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