IRBs Navigating the Ocean of Apps

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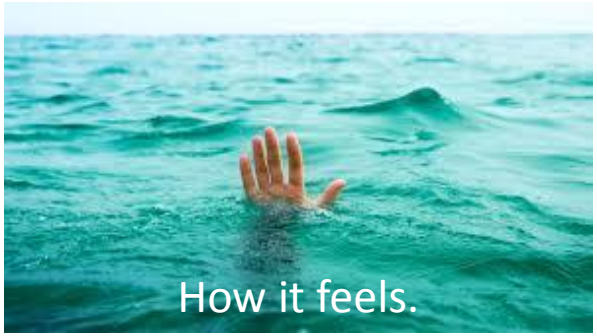

mHealth Promises

For clinical care

- Reach more people - remote access
- Access to more real-time real-life data
  - Expanded feed
  - May be able to look at behaviors and social interactions
- Improve retention and compliance

For Research

- Reach more people – remote access
- Gather more information
  - Physiological parameters continuously in real-time
  - Behavior
  - Environmental exposure
  - Social interaction
  - GPS
- Improve retention and compliance

The IRB

- What information does the IRB need to:
  - Assess the risk-benefit
  - Determine what should be included in the consent form?
- What ‘ancillary help’ is needed to help with these assessments?

What does an IRB need to know about:
General App information?

- How many apps and what is their status?
  - Marketed app?
  - New app?
- Is the app approved? By whom? For what?
- What is the accuracy of the data?
- What is the security of the app?
- What does the app platform keep/have access to?
- Will the data be shared? If so with whom? When?
- Will data be placed in the medical chart?
- Is there a EULA (End User Licensing Agreement)?
  - Is it comprehensible?

What does the IRB need to know about:
General App Information?

- What is the user interface?
  - What does a user need to do to operate?
  - How to monitor app use
- Data flow
  - Passive
  - Active
    - What (e.g., Parkinson's screen tapping, diary entry)
    - When (e.g., routine schedule, on prompt)
    - How often?
    - Where (e.g., while driving, in school)
  - Is data about close contacts captured?

What does the IRB need to know about:
The Participants?

- Who are they?
  - Vulnerable and/or small group?
  - Sensitive disease/condition
- What is their Experience with devices and apps?
  - Naïve, first-time app-users?
  - If experienced - may be a biased population!
  - Will they use their own device/app or will the study provide one
    - If provided, what happens if lost? Stolen? End of study?
    - If not provided –is there a cost to the participant's plan?

What does the IRB need to know about:
Subject Engagement and Retention?

- Differences between the ‘routine-app-user’ and the ‘app-naïve-user’
- Duration and intensity of the ‘intervention’
- Are there incentives to maintain engagement?
- Does the study design and statistical plan account for possible retention problems

What does the IRB need to know about:

Privacy and Security?

- Privacy Policy of the app/s
- Specifically ask:
  - Who has access to the data? (App platform, 3rd parties)
  - Will data from other sources be merged with the study data?
    - E.g., if 23andMe, how does this change identifiability? Risk?
  - Secondary uses of the data by the app 'owner'
    - Specifically any commercial uses?

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What should the IRB do about:

Informed Consent?

- Will consent be remote? Or in person?
  - Comprehension?
  - Opportunity for asking questions?
- Consent should include:
  - Details about the app
    - Privacy and security issues – in an understandable presentation
    - EULA details – in an understandable presentation
  - Where their information will go and how it may be used.
  - Any costs:
    - For the device, the app, increased phone use time.
    - Responsibility if lost etc.
  - Ability to withdraw from the study
    - Any special limitations with apps?

Oversight of apps: a team effort

The non-IRB team

- Research information security
  - Assess control and security measures re: transmission, storage, destruction of data
- Biomedical engineering
  - If electrical safety is an issue
- FCC
  - If concern of interference from wireless devices
- Clinical Trials office
  - Review of EULAs, Terms of Use, Privacy terms, Data Use Agreements
- Office of General Counsel
- Medical Records
  - If data is to be returned to the medical record
  - May also require consultation with clinical services

Oversight of apps: a team effort
Timing of non-IRB team input

- IRBs must identify what information is needed to make risk assessment and determine ICF details
  - These reviews should precede IRB review
- Example:
  - Partners HealthCare
    - An institutional ‘App-Wrangler’ to coordinate the various reviews
    - At a minimum, Research Information Security and Clinical Trials Office sign-off are required before the IRB will review the protocol

Common Responses from Investigators

- “These apps are being used for clinical care – why is the IRB being so picky?”
- “These people already have their own Smart phone with this app – why is the IRB being so picky?”

Summary

- Apps and mhealth apps are everywhere
  - And not going away
- IRB and non-IRB oversight is needed
- Challenges in research oversight
  - User interface
  - Secondary use
  - Privacy and security
  - Informed consent

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