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VIRTUAL RESEARCH: CONSIDERATIONS FOR SITE IMPLEMENTATION

Prepared for
SCORE

Date
October 21, 2020

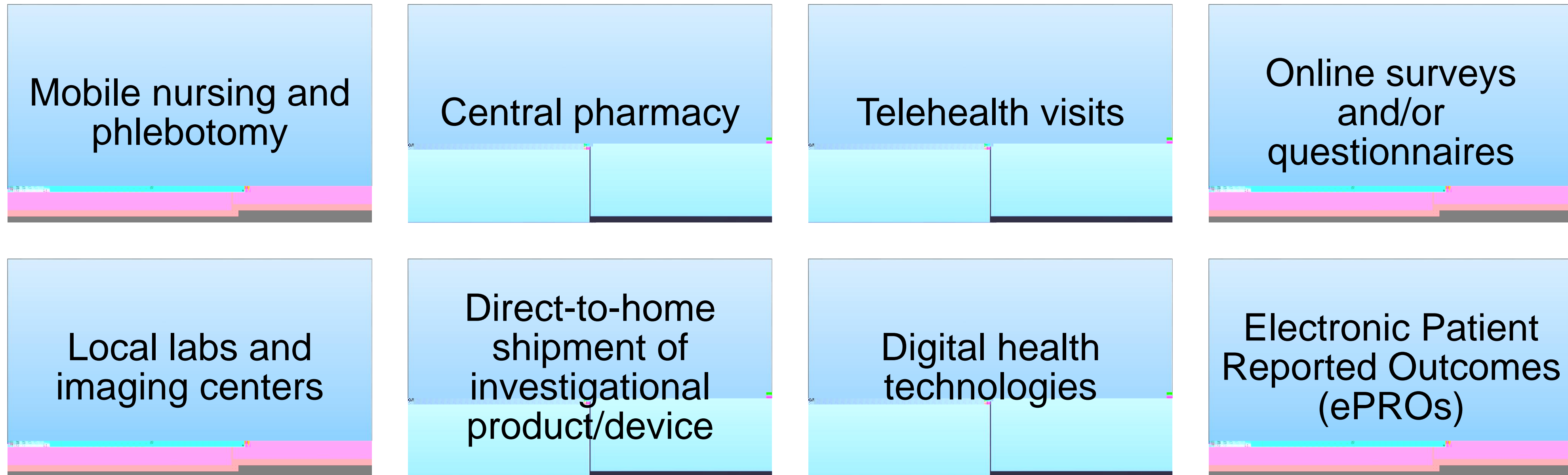
INTRODUCTION TO VIRTUAL RESEARCH

The use of **digital health technologies** and **social engagement platforms** to conduct clinical trials.

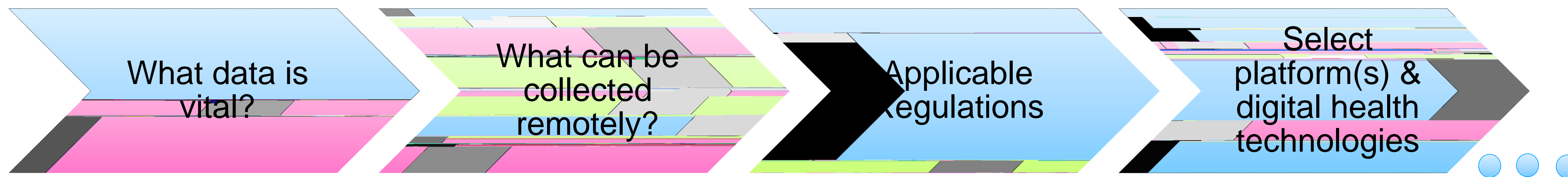
Introduction to Virtual Research

E. Baloga

Virtual Components

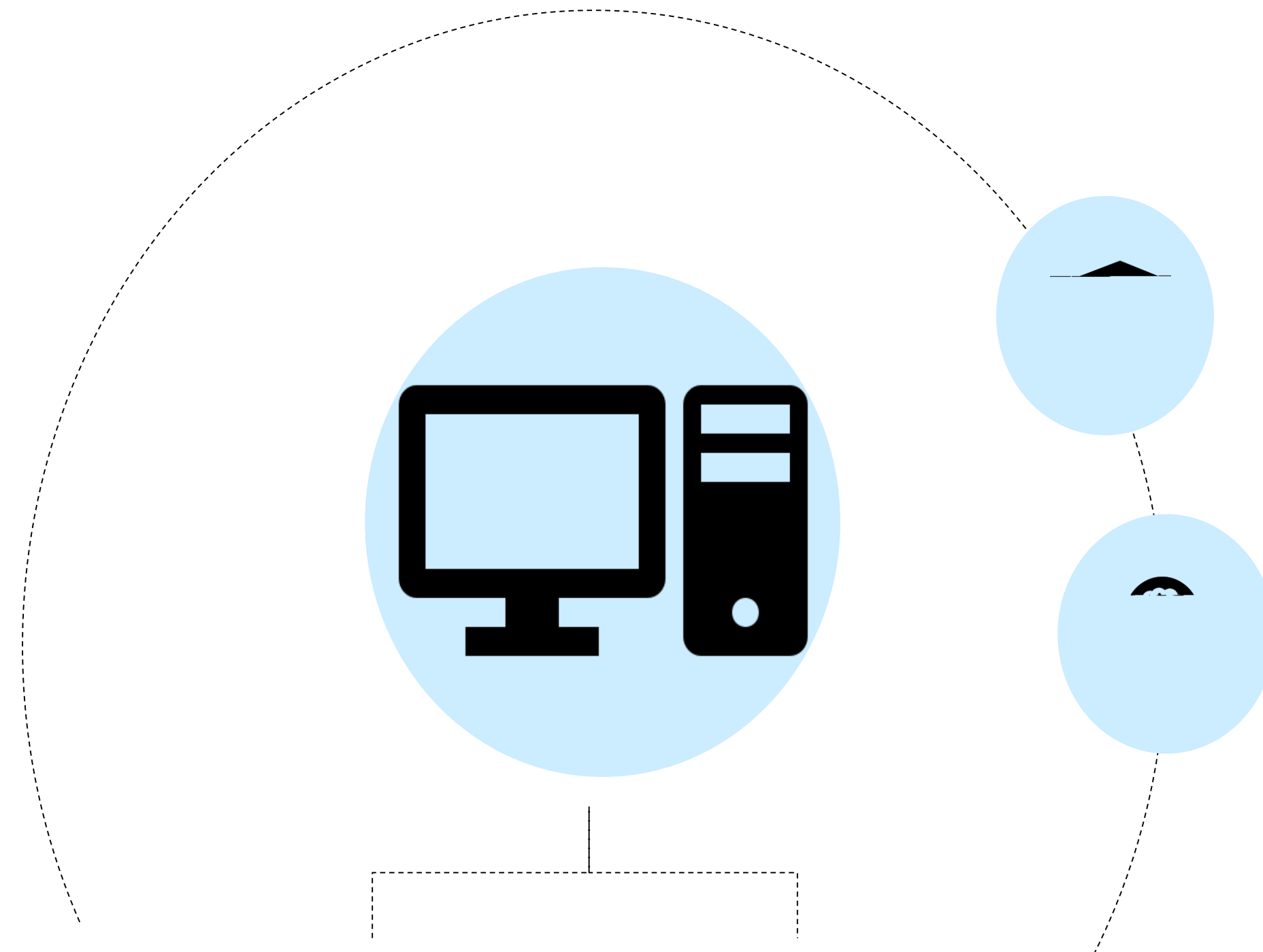


Transitioning from Traditional to Hybrid or Virtual



HIPPA

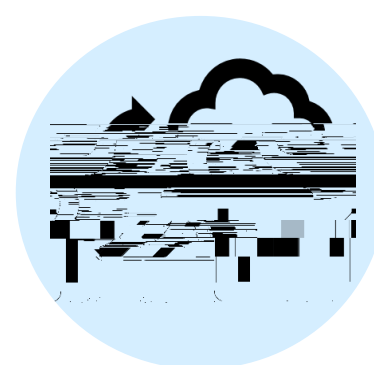
Components



eConsent within REDCap

Digital method for collecting and storing informed consents

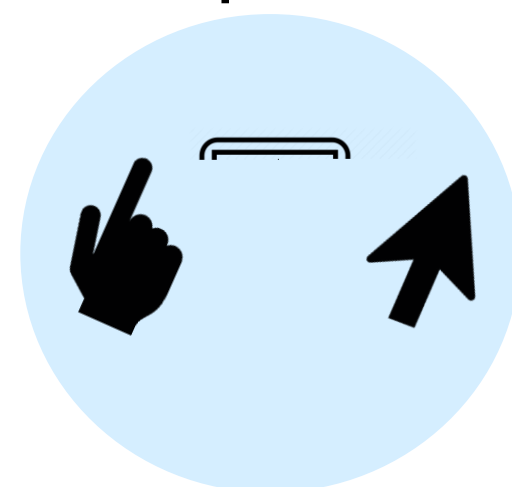
Uses e-Consent Framework and PDF Auto-Archiver



Compatible with multiple platforms - Computer, mobile phone, or tablet



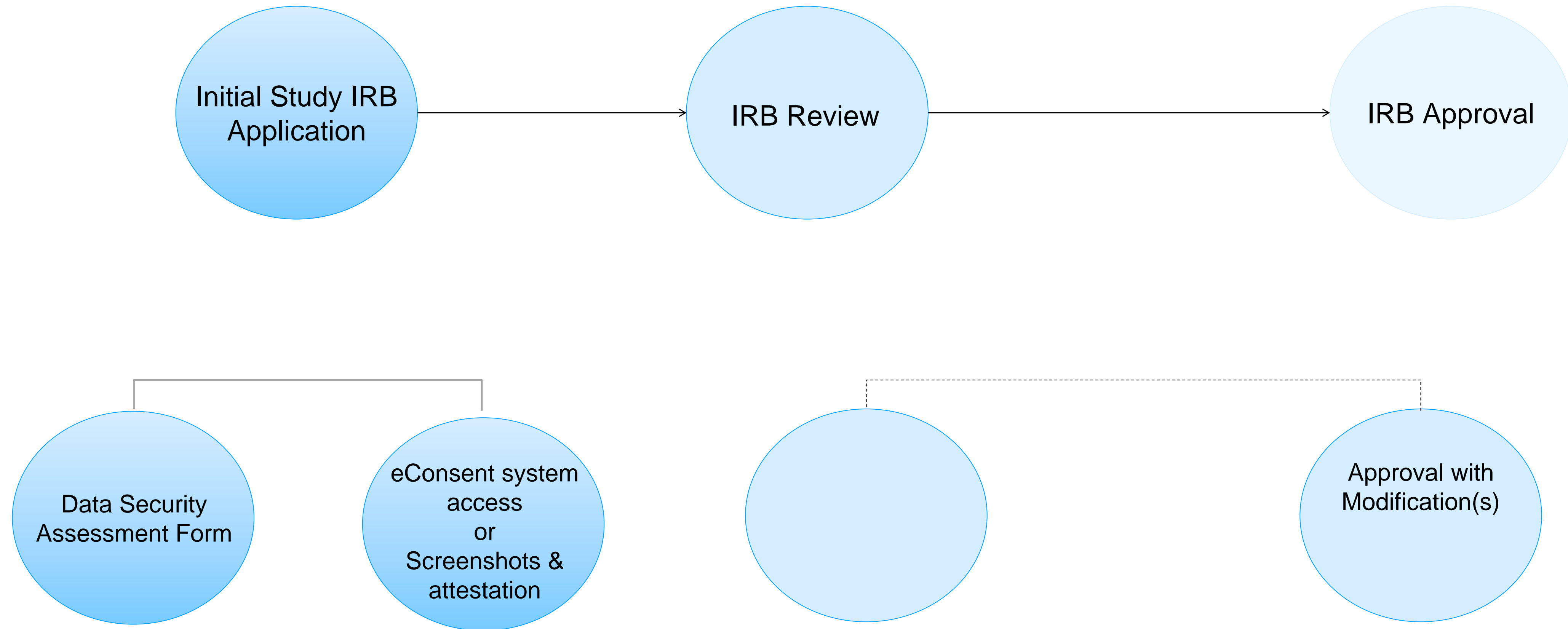
eSignature flexibility finger, stylus, or mouse



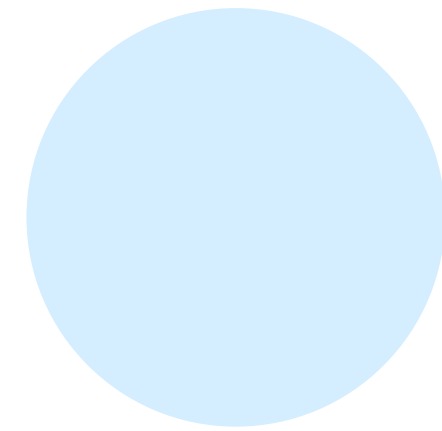
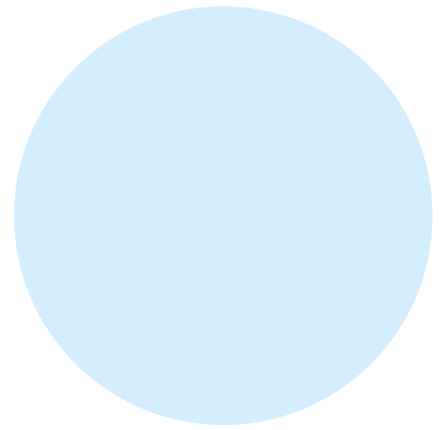
Provides copy of the signed form via downloadable pdf, and/or receipt via email with PDF attachment



IRB Approval Process



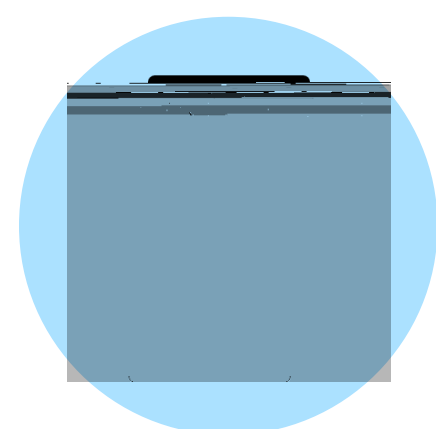




S. Jensen-Roberts



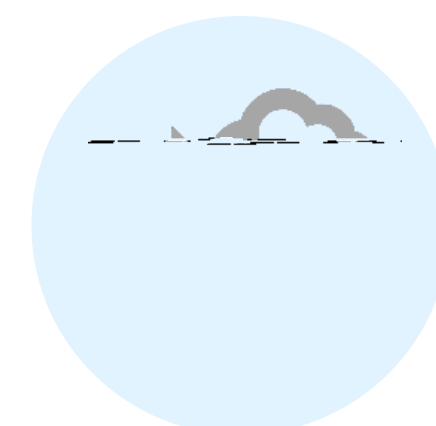
Platform Options



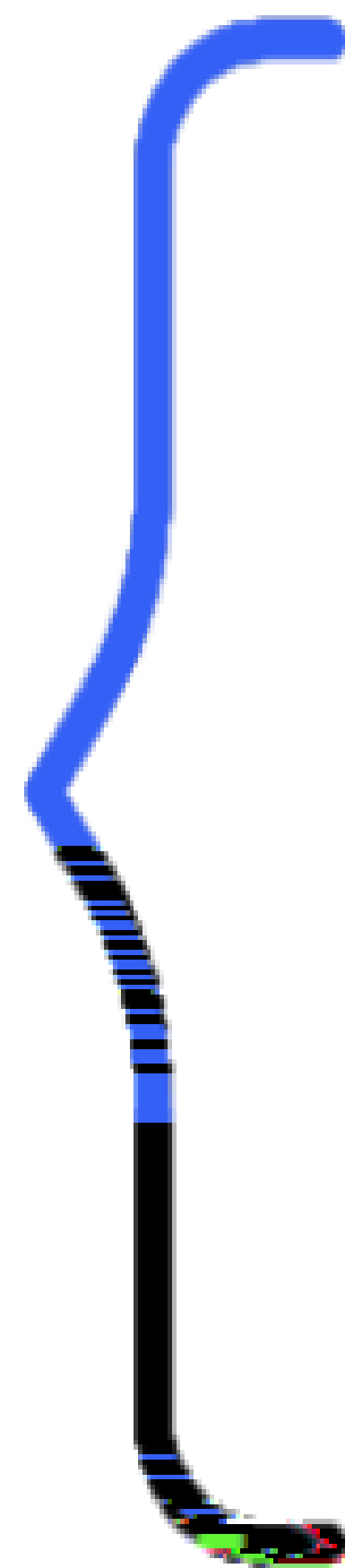
Smartphone Applications



Wearables



Passive Devices



Features and Capabilities

Accelerometer
Step Counter (Passive)

Gyroscope
Heart Rate

Pros

Cons

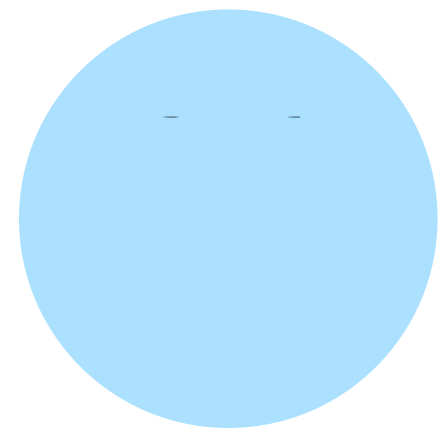
Directed Activities
Accessibility
Ease of use
Real-time data

Compliance
Technical Support
Needed

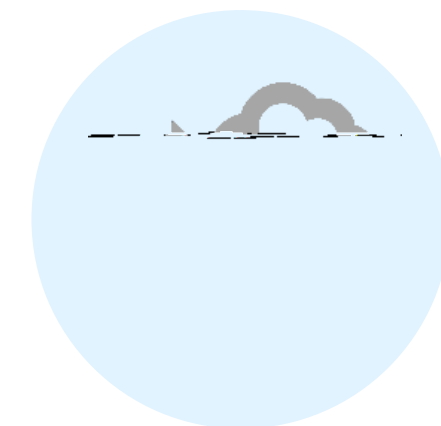
Platform Options



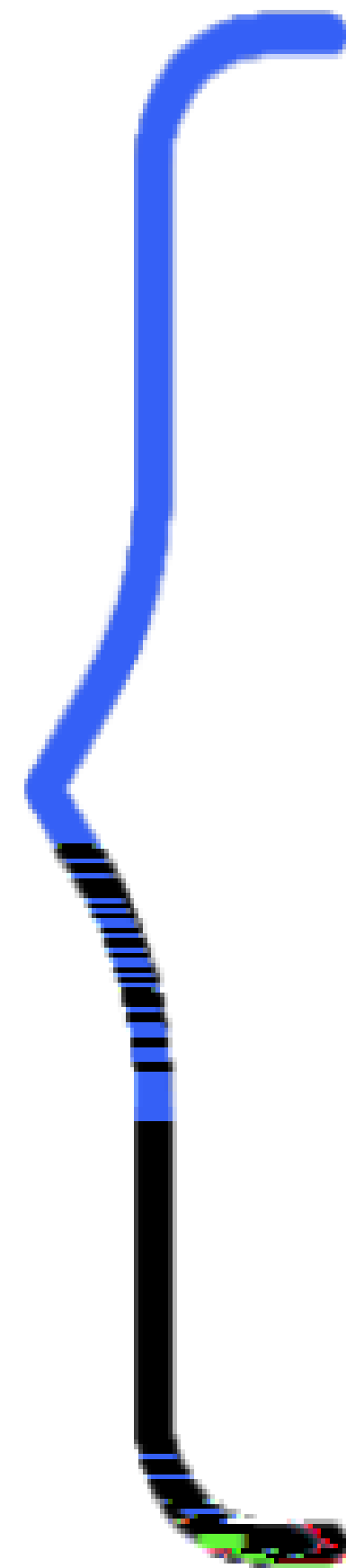
Smartphone Applications



Wearables



Passive Devices



Features and Capabilities

Accelerometer
EKG
Temperature

Blood Monitoring
Gait and Posture
Motion Detection

Pros

Cons

Activity Completion
Activity Levels
Sleep Data
Real-time data
Vital Signs

Compliance
Comfortability
Remembering to apply
and recharge if needed
Difficulty of Application

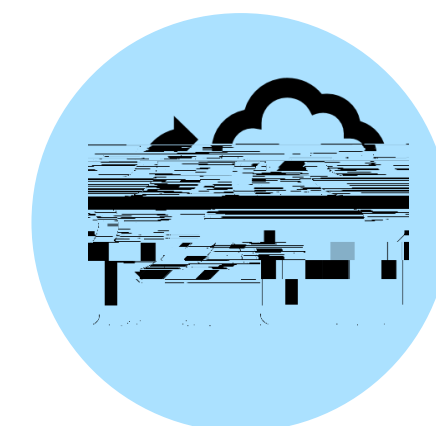
Platform Options



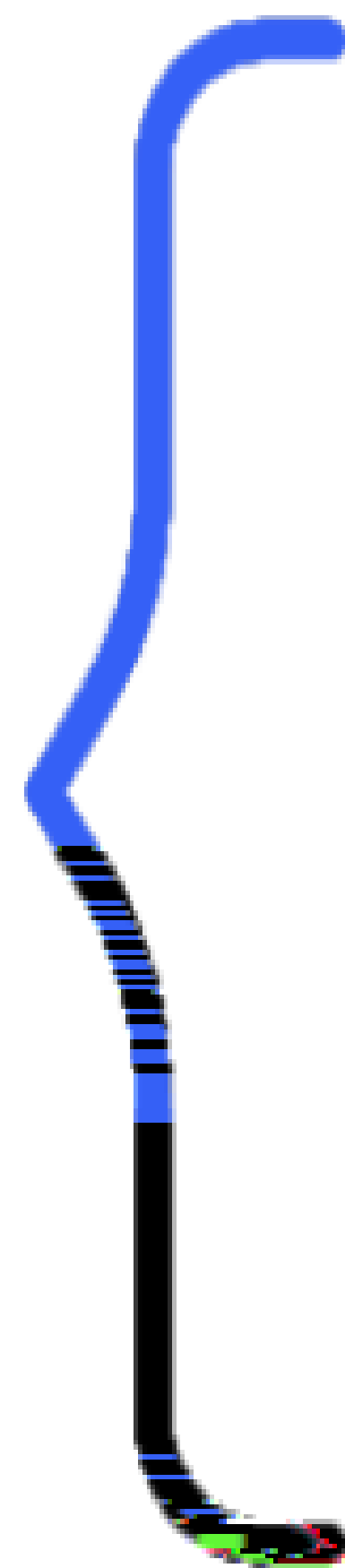
Smartphone Applications



Wearables



Passive Devices



Features and Capabilities

Radio Waves
Activity Levels

Sleep
Vital Signs

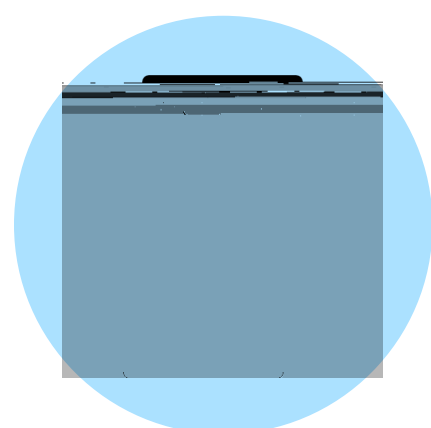
Pros

Cons

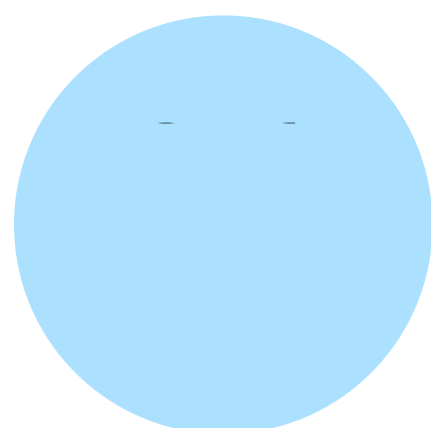
Movement Patterns
Captured
Data on Habits
Sleep Data
Real-time Data
Respiration Data

Confounding Variables
Privacy Concerns
Technical Support
Needed
Geographically Limiting

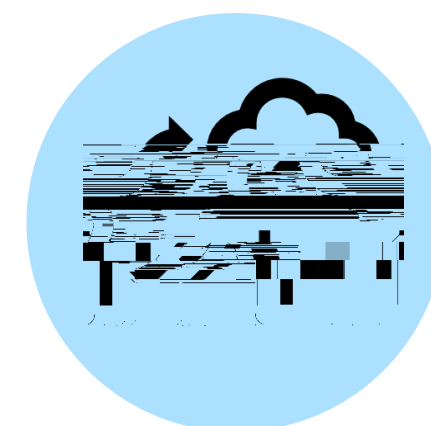
Important Considerations



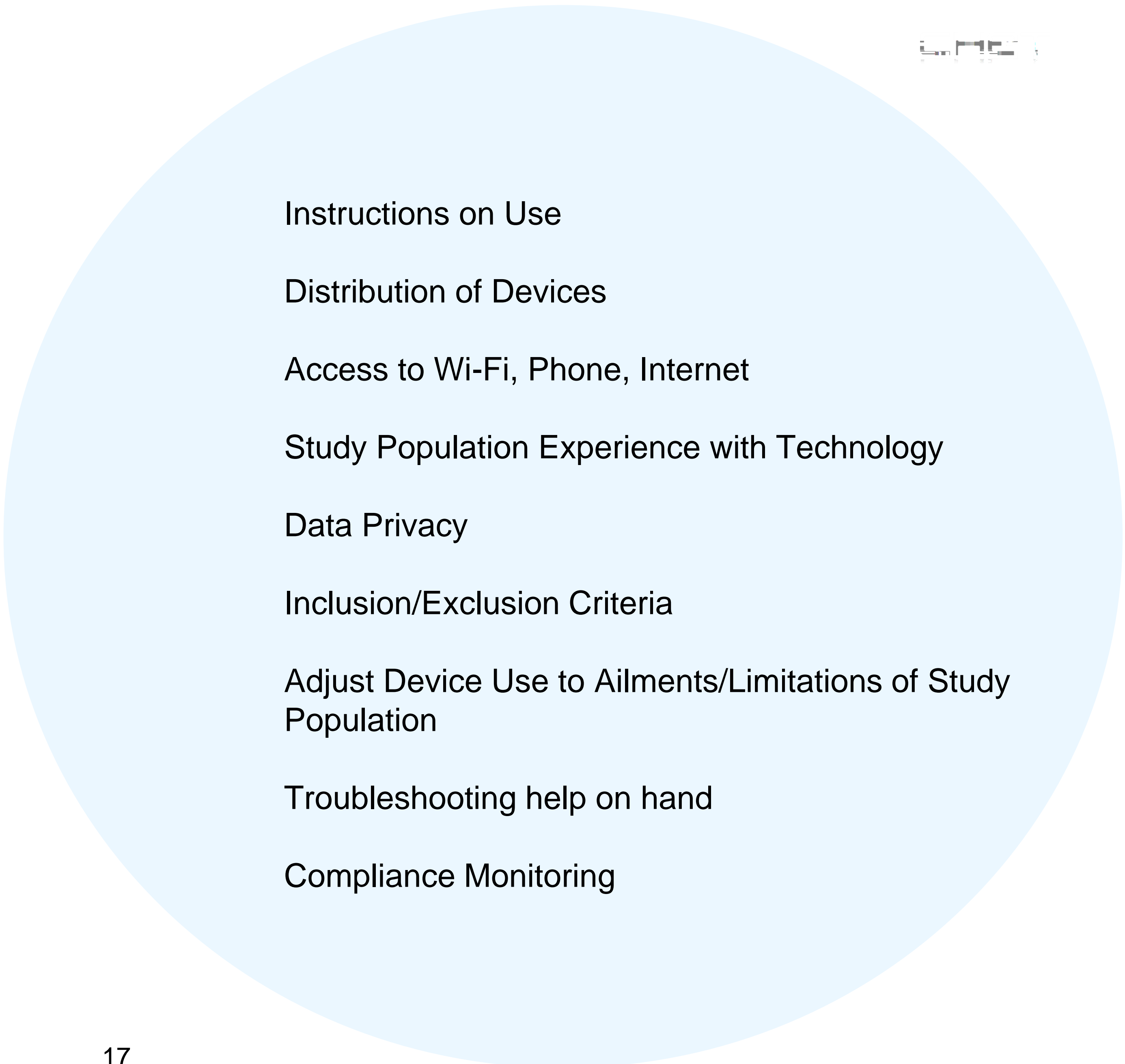
Smartphone Applications



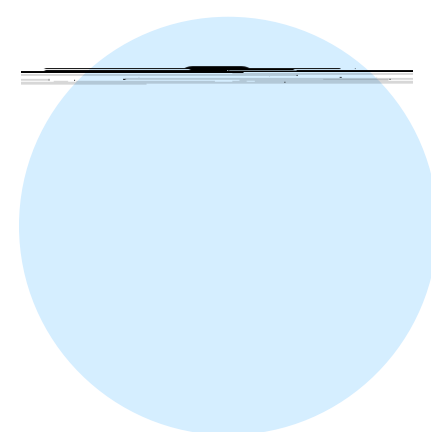
Wearables



Passive Devices

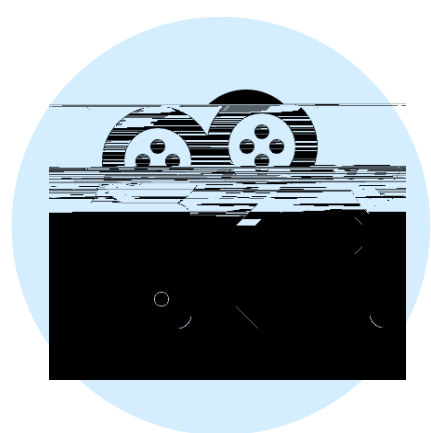


PRO Surveys, Video Platforms



Patient Report Outcome (PRO) Surveys

- REDCap
- Trial Master 5.0
- Medidata Rave
- Google Forms
- Survey Monkey



Video Platform Options

- Zoom for Healthcare
- GoToMeeting
- Microsoft Teams
- Many others, with more capabilities

Important Considerations

All HIPAA compliant
REDCap is 21 CFR Part 11 Ready
Trial Master 5.0 and Medidata Rave are 21 CFR Part 11 compliant

Video Platform Options

When selecting the platform, seek out a vendor is both HIPAA compliant and one that is intending to enter into a HIPAA business associate agreement (BAA). A list of these can be found on [HHS.gov](https://www.hhs.gov)

Questions?

