

VIRTUAL RESEARCH: CONSIDERATIONS FOR SITE IMPLEMENTATION

Prepared for
SCORE

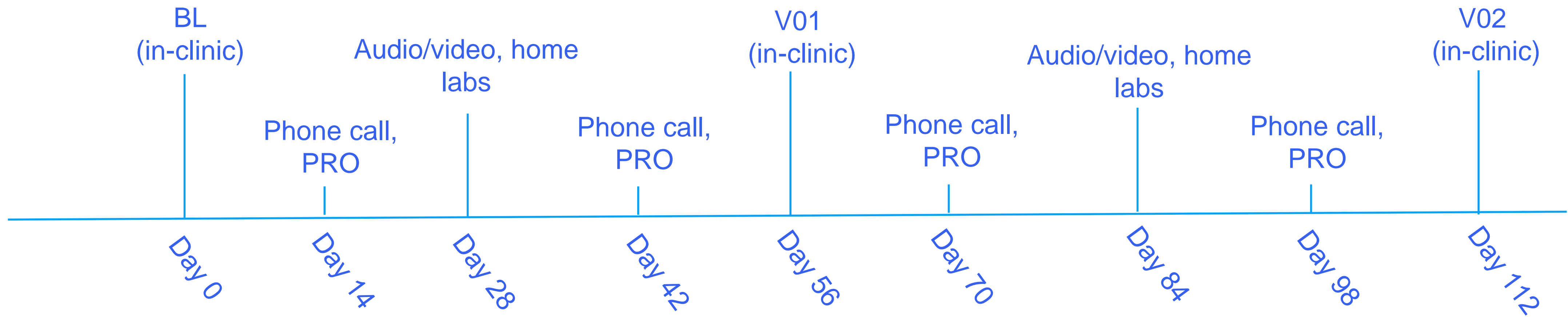
Date
October 21, 2020

02	INTRODUCTION TO VIRTUAL RESEARCH
08	ELECTRONIC INFORMED CONSENT
12	DIGITAL TECHNOLOGIES
18	Q & A

What does “virtual research” mean?

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

Virtual research does not have to be an all-or-nothing approach. **Hybrid Trials use a combination of both virtual and traditional (in-person) visits.**



Virtual Components

Mobile nursing and
phlebotomy

Central pharmacy

Telehealth visits

Online surveys
and/or
questionnaires

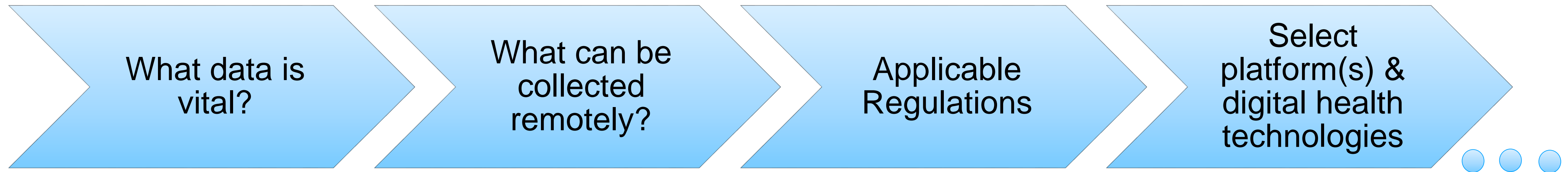
Local labs and
imaging centers

Direct-to-home
shipment of
investigational
product/device

Digital health
technologies

Electronic Patient
Reported Outcomes
(ePROs)

Transitioning from Traditional to Hybrid or Virtual



HIPPA

www.hhs.gov/hipaa

- Privacy Ruling
- Security Ruling
- Breach Notification Ruling

21 CFR PART 11

www.fda.gov/cfr

- Electronic Systems requirements
- Electronic Systems validations

FDA GUIDANCE

www.fda.gov/guidancedocuments

- Computerized systems used in clinical investigations
- Electronic informed consent in Clinical Investigations
- Electronic Source Data in Clinical Investigations
- Part 11, Electronic Records; Electronic Signatures

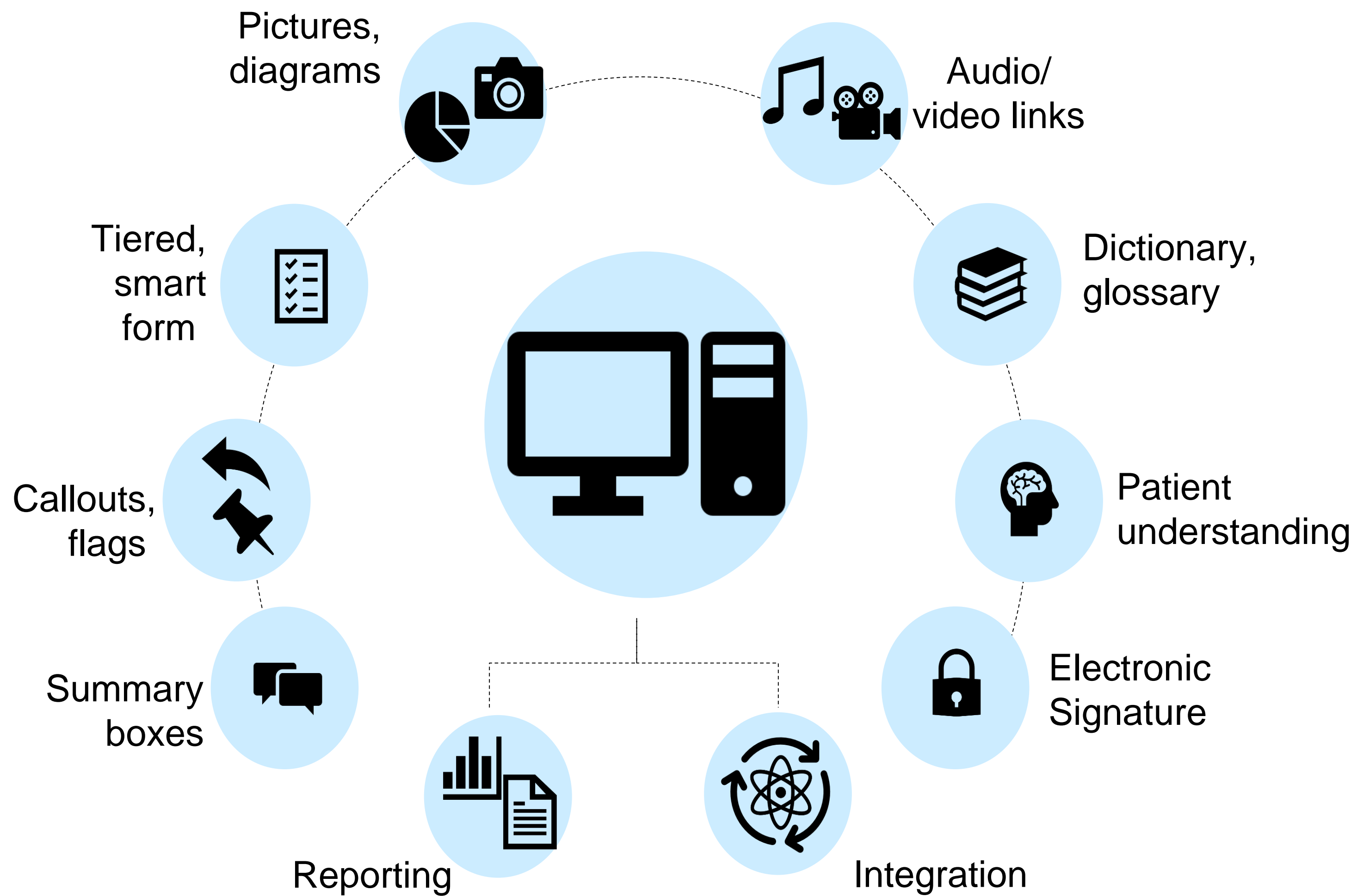
ESIGN ACT

www.govinfo.gov/esignact

- Electronic Signatures legal validity
- NYS – Electronic Signatures and Records Act

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Components



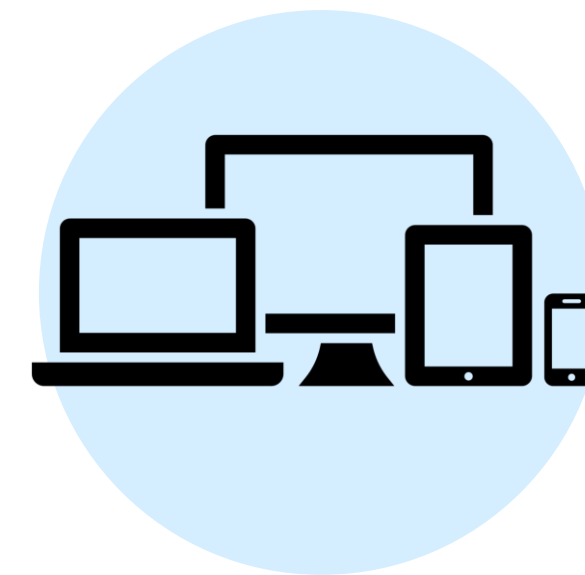
eConsent within REDCap

Digital method for collecting and storing informed consents

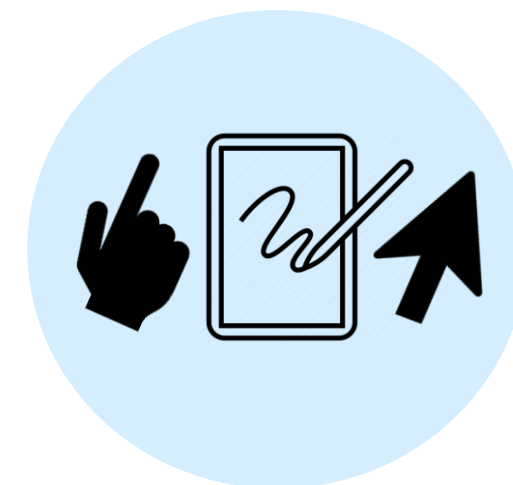
Uses e-Consent Framework and PDF Auto-Archiver



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



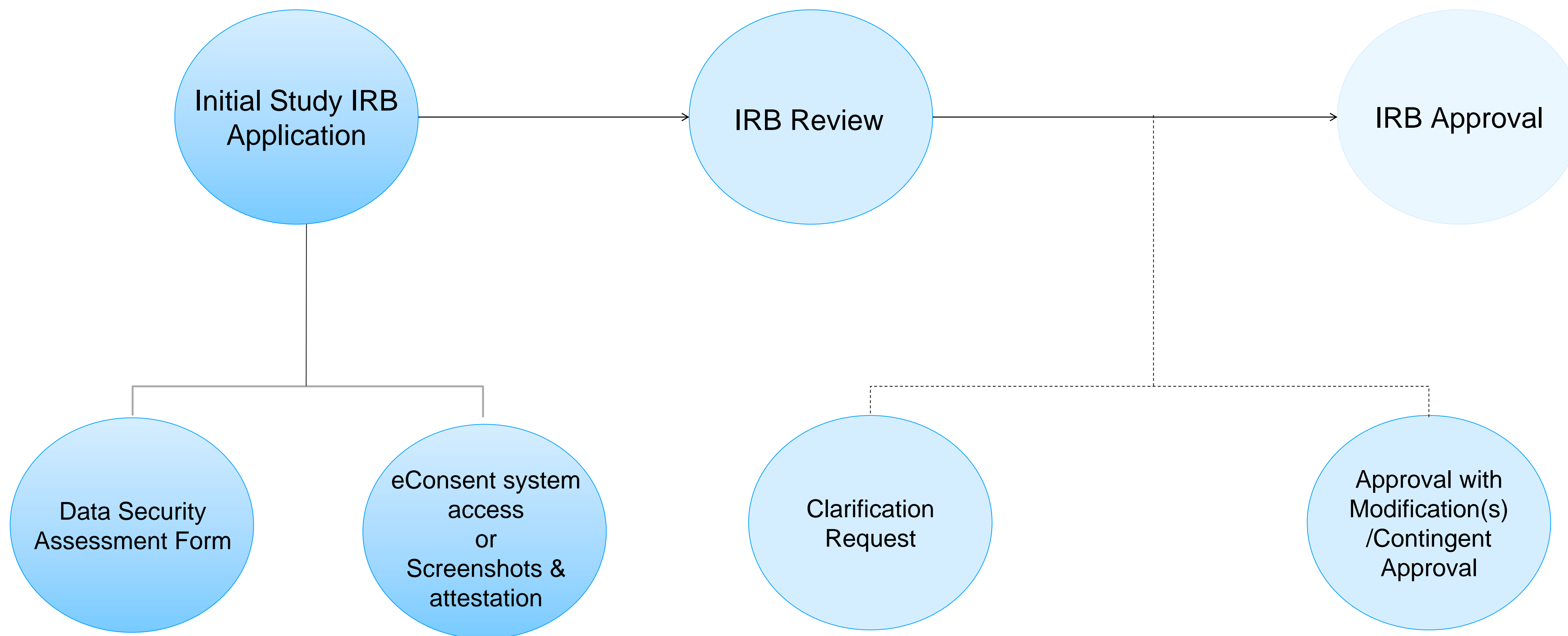
eSignature flexibility – finger, stylus, or mouse



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



IRB Approval Process



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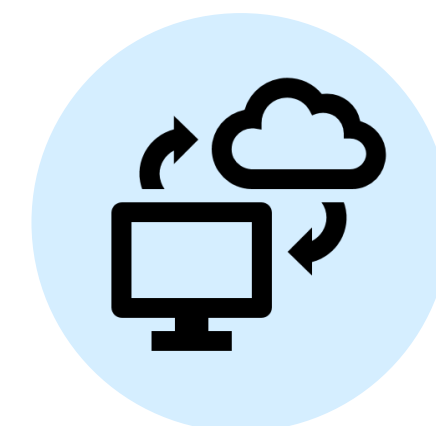
Digital Technology Options



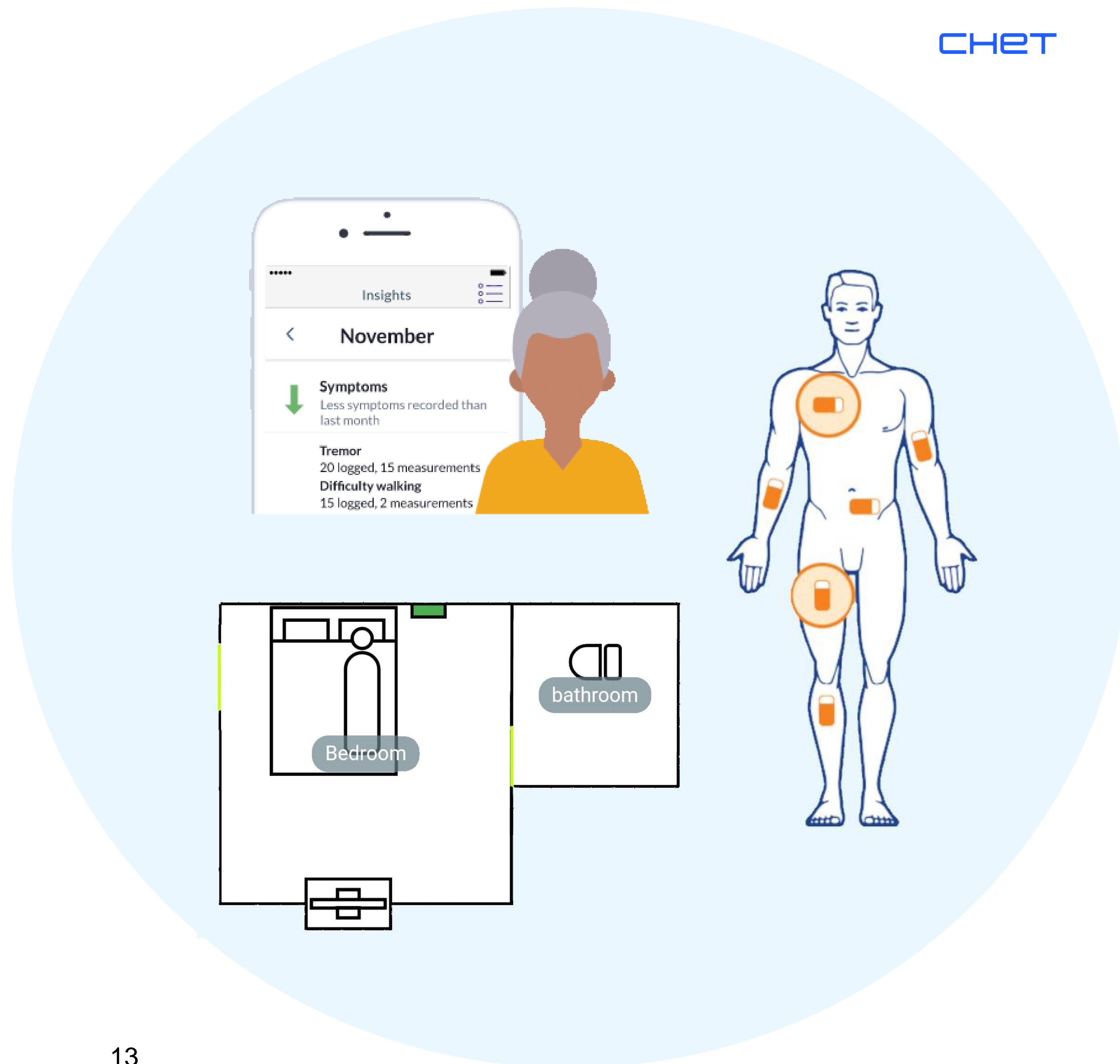
Smartphone Applications



Wearables



Passive Devices



Platform Options



Smartphone Applications



Wearables



Passive Devices



Features and Capabilities

- Accelerometer
- Step Counter (Passive)
- Gyroscope
- Heart Rate

Pros	Cons
<ul style="list-style-type: none">• Directed Activities• Accessibility• Ease of use• Real-time data	<ul style="list-style-type: none">• Compliance• Technical Support Needed

Platform Options



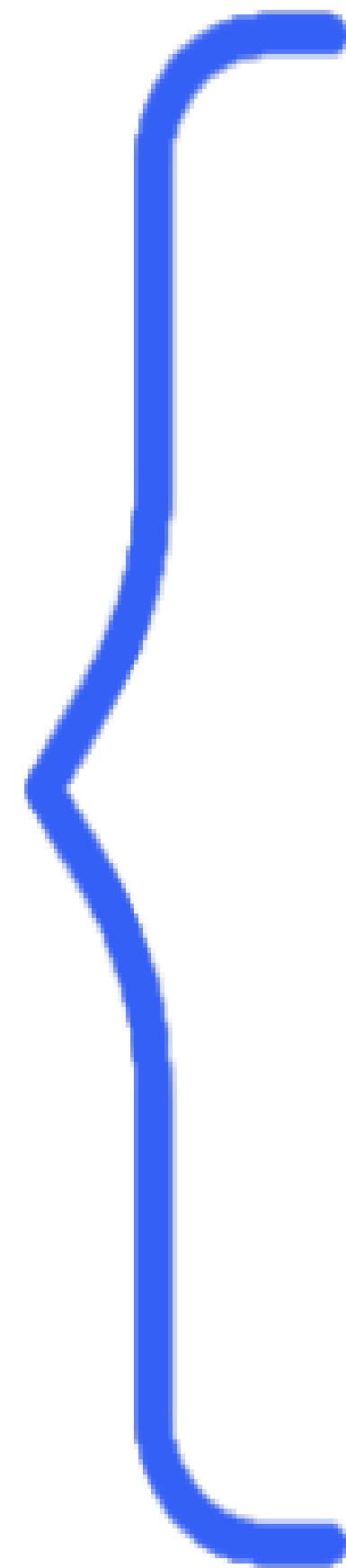
Smartphone Applications



Wearables



Passive Devices



Features and Capabilities

- Accelerometer
- EKG
- Temperature
- Blood Monitoring
- Gait and Posture
- Motion Detection

Pros	Cons
<ul style="list-style-type: none">• Activity Completion• Activity Levels• Sleep Data• Real-time data• Vital Signs	<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• Movement Patterns Captured• Data on Habits• Sleep Data• Real-time Data• Respiration Data	<ul style="list-style-type: none">• Confounding Variables• Privacy Concerns• Technical Support Needed• Geographically Limiting

Important Considerations



Smartphone Applications



Wearables



Passive Devices

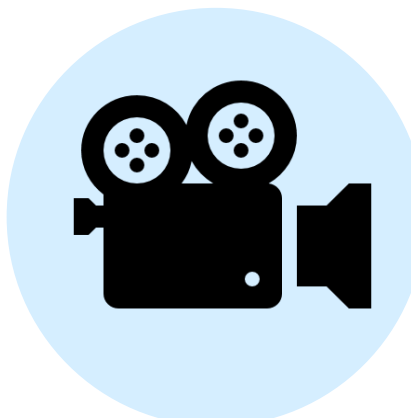
- Instructions on Use
- Distribution of Devices
- Access to Wi-Fi, Phone, Internet
- Study Population Experience with Technology
- Data Privacy
- Inclusion/Exclusion Criteria
- Adjust Device Use to Ailments/Limitations of Study Population
- Troubleshooting help on hand
- Compliance Monitoring

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

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Questions?

