

# 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



## Virtual Components

Online surveys Mobile nursing and Central pharmacy Telehealth visits and/or phlebotomy questionnaires Direct-to-home Electronic Patient Digital health shipment of Local labs and Reported Outcomes technologies investigational imaging centers (ePROs) product/device

E. Baloga



## Transitioning from Traditional to Hybrid or Virtual

What data is vital?

What can be collected remotely?

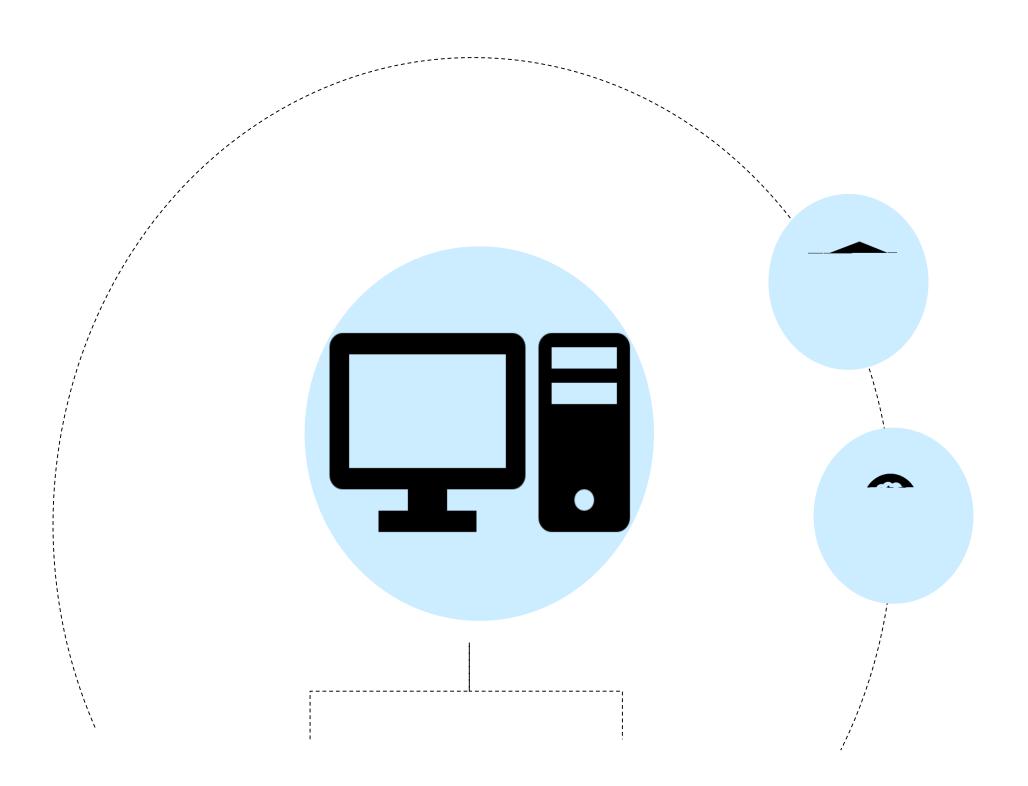
Applicable digital health technologies

# HIPPA

E. Baloga

Electronic Informed Consent

# Components



# eConsent within REDCap

Digital method for collecting and storing informed consents

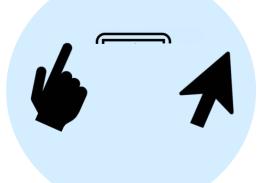
Uses e-Consent Framework and PDF Auto-Archiver



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



eSignature flexibility finger, stylus, or mouse

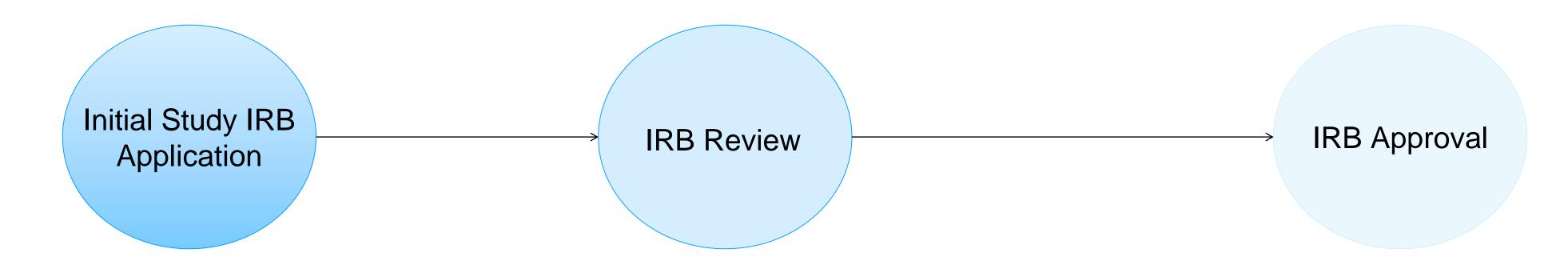


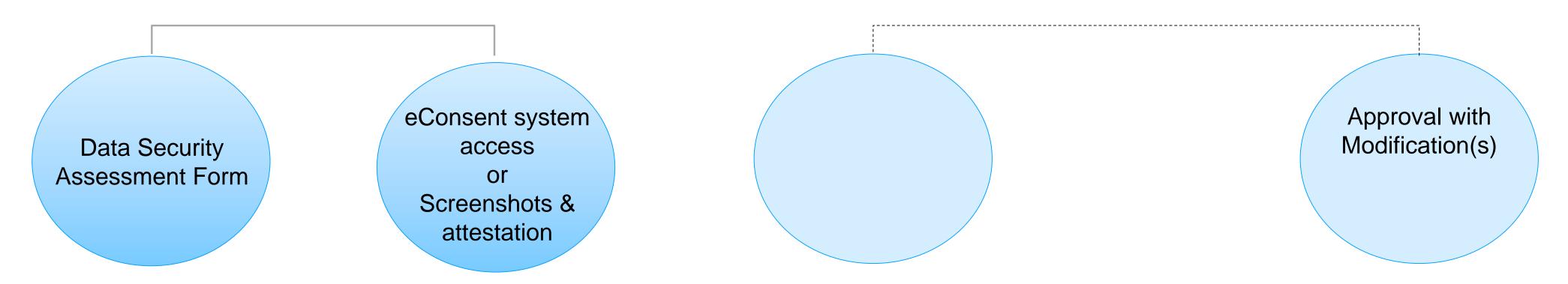
Provides copy of the signed form via downloadable pdf, and/or receipt via email with PDF attachment





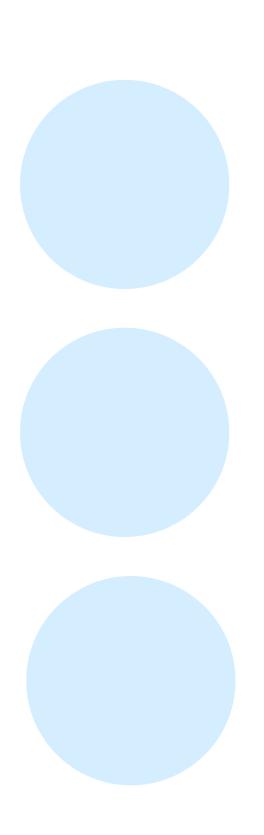
## IRB Approval Process





S. Duquette

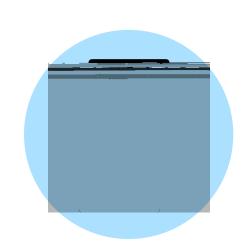




S. Jensen-Roberts



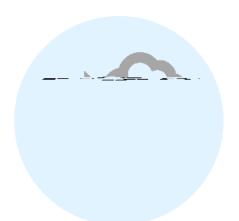
# Platform Options



## **Smartphone Applications**



Wearables



**Passive Devices** 

S. Jensen-Roberts

### **Features and Capabilities**

Accelerometer
Step Counter (Passive)

Gyroscope Heart Rate

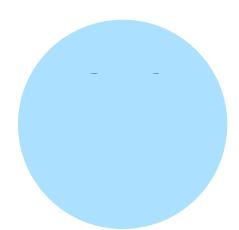
Pros	Cons
Directed Activities Accessibility Ease of use Real-time data	Compliance Technical Support Needed



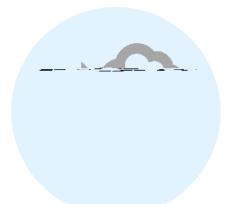
# Platform Options



## **Smartphone Applications**



#### Wearables



#### **Passive Devices**

S. Jensen-Roberts

#### **Features and Capabilities**

Accelerometer EKG Temperature Blood Monitoring Gait and Posture Motion Detection

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

Pros

#### Cons

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



# Platform Options



## **Smartphone Applications**



Wearables



**Passive Devices** 

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#### **Features and Capabilities**

Radio Waves Activity Levels

Sleep Vital Signs

#### **Pros**

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

#### Cons

Confounding Variables

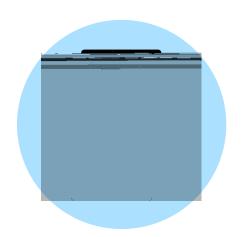
Privacy Concerns

Technical Support Needed

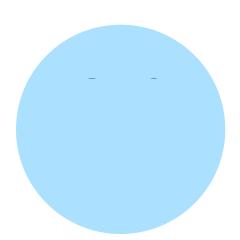
Geographically Limiting



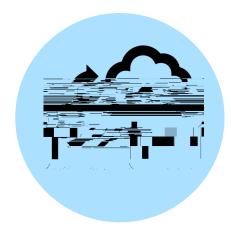
# Important Considerations



## **Smartphone Applications**



Wearables



**Passive Devices** 

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Instructions on Use

Distribution of Devices

Access to Wi-Fi, Phone, Internet

Study Population Experience with Technology

**Data Privacy** 

Inclusion/Exclusion Criteria

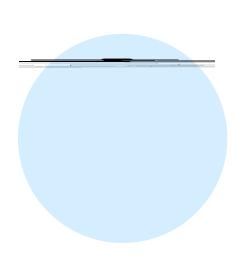
Adjust Device Use to Ailments/Limitations of Study Population

Troubleshooting help on hand

**Compliance Monitoring** 

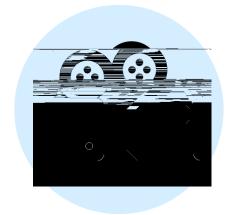


# PRO Surveys, Video Platforms



## 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

#### S. Jensen-Roberts

#### **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

# Questions?

