THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

REDCap eConsent Template

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OSU

REDCap Services

- **Grand Rounds**
  - Second Tuesday of Every Month at 11am
- **Office Hours**
  - Mondays from 11am-1pm and Wednesday from 1pm-3pm
  - Zoom link
- **Monthly Trainings**
  - Last Wednesday of Each Month at 12pm
- **Thursday Consults**
  - Scheduled
- **Form Reviews**
  - Scheduled

eConsent

Introduction

- Electronic informed consent (eConsent) is a method of obtaining informed consent using electronic media (i.e REDCap)
- Can supplement or replace paper-based informed consent forms, and be used in-person and/or remotely
- In order to use eConsent for a study, IRB approval must be obtained

eConsent

Benefits

- Aids in conducting remote consent
- Improves the participant experience
  - Easy-to-follow interface
  - Ability to integrate graphic or video content
- Streamlines the consent process and maintenance of consent forms
  - Regulatory
  - Participant History

eConsent

IRB Requirements

- The IRB must approve the use of eConsent for the study

- Three primary methods for conducting eConsent
  - Remote
  - In-Person
  - Combination of Remote and In-Person

- Participant signature
  - IRB will need to determine if a participant signature is required
  - Approved method for obtaining signature
    - In-person
    - Pre-established passcode
    - Using information known to the participant, which is stored in REDCap
      - Using PHI/PII as a passcode is the last resort

eConsent

REDCap Template: Rolling Out First Quarter 2022

- Study staff will document informed consent procedures using the approved COM eConsent REDCap template

- REDCap features
  - Consent version tracking and control
  - Contact log tracking
  - Verification using passcode with survey login
  - eConsent framework

- At this time, REDCap cannot be used to collect eConsent on FDA-regulated studies as REDCap is not yet compliant with 21 CFR Part 11

- New eConsent template expected rollout timeframe: first quarter of 2022

- Demo

eConsent

REDCap Request Process: Rolling Out First Quarter 2022

- To utilize REDCap eConsent, a new REDCap project request form must be submitted
- Once received, a REDCap Administrator will assist the study team with building and configuring the REDCap project based on the IRB approved methods for the study
- A meeting will be scheduled with the study contact listed on the request form to review the REDCap eConsent procedures and project setup, and finalize settings
- The eConsent project will be deployed by REDCap adminstrators once IRB approval has been obtained, documented, and verified
    - IRB approved documents must be uploaded, and consent history related information documented in the REDCap eConsent project

Announcements

Next Sessions

- **Monthly Training**
  - December 22 at 12pm
  - REDCap for Data Entry and Program Management
  - Registration link coming soon
  - Training page
- **Grand Rounds**
  - January 11 at 11am
  - REDCap Version 11
  - Registration link