E-Consent: Benefits, Challenges, and Considerations

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Poll: Have you ever worked on a study that utilized e-Consent?

a. Yes, before the COVID-19 pandemic
b. Yes, but only after the COVID-19 pandemic started
c. No

Poll: Do you have experience with REDCap, or the REDCap e-consent framework?

a. Yes, I have experience with REDCap but not the REDCap e-consent framework
b. Yes, I have experience with both REDCap and the REDCap e-consent framework
c. No, I do not have experience with REDCap

What is Informed Consent?

- Required when doing Human Subjects Research
  - 45 CFR 46
- Consent is the most important protector of a participant's **autonomy**
  - **Informed consent is a process**
- Must involve info needed to make an informed decision about participating
  - Reasonable person standard
  - Sufficient and organized
- Written Consent includes signature/date of person who wants to participate and staff who performed the consent
  - Other items, depending on site/study

What is e-Consent?

- Put simply: *electronic* consent
- Requires participant and staff to sign on a device
  - Stored in a secure, HIPAA-compliant system
- Relatively new to research, but not new to people
- Different methods depending on research study
  - Participant facilitated
  - Researcher facilitated
- **Remote** or in-person
  - Remote will be the focus of this presentation

E-consent: Regulatory Basics

- Common Rule (1991, revised 2018) → transparency, increasing understanding
- Elements of informed consent and the documentation requirements for human subjects → HHS and/or FDA regulations:
  - 45 CFR § 46.116 → General Requirements for Informed Consent
  - 21 CFR § 50.25 → Elements of Informed Consent
  - 45 CFR § 46.117 and 21 CFR § 50.27 → Documentation of Informed Consent
  - 21 CFR 50.20 → FDA General Requirements for Informed Consent
- E-consent forms, like hard-copy consent forms, must include all elements of informed consent as required by HHS and FDA

E-consent vs. Paper consent - What do they have in common?

- ***Consent forms*** *must….*
  - Contain all elements of informed consent as required by HHS and/or FDA regulations
  - Be written in accessible language, clear and easy to navigate
  - Be approved by the IRB
- ***Investigators*** *must…*
  - Ensure that effective informed consent is obtained before enrollment
  - Document signatures and store all signed consent forms
  - Archive all versions of the consent form

E-consent vs. Paper consent - Key differences

- Potential for remote e-consent process
- ***How will you…***
  - Answer questions?
  - Assess comprehension and facilitate understanding?
  - Verify participant identity before signing?
    - Password, reviewing state-issued identification, security questions, etc.
    - Risk-based approach (minimal vs. greater than minimal risk research)

Chat storm!

If you have been part of a study that utilized e-consent, what platform(s) did you use?

Electronic systems

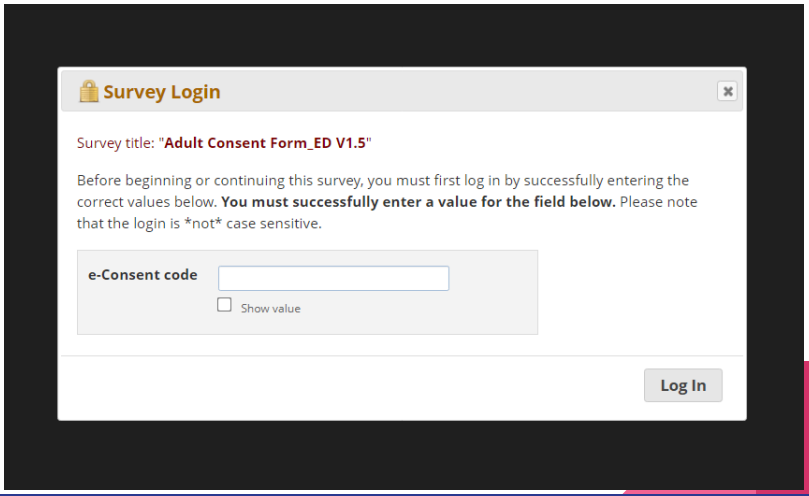
- Various platforms may be suitable for e-consent
  - REDCap
  - DocuSign
  - Hundreds of others!
- *Considerations…*
  - Confidentiality-- keep all data separate
  - Encryption (HIPAA covered entities)
  - SOPs/guidance documents to address issues
  - **Compliant with regulatory requirements**
    - Does this platform meet my research, administrative, technical and financial needs?

Platform Highlight: REDCap

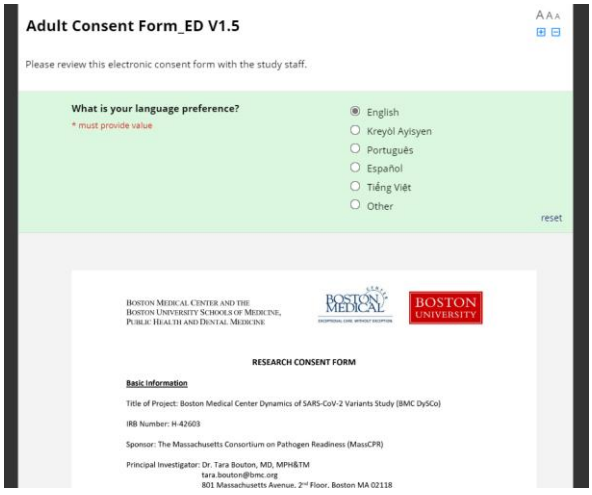
- **R**esearch **E**lectronic **D**ata **Cap**ture
- Secure web application for building and managing online databases in a HIPAA-compliant environment
- Great data collection resource → e-consent framework
  - Password protecting e-consent forms
  - Digital signatures
  - Generates PDF of signed consent form
  - Multi-signature options available

E-Consent Examples - REDCap

REDCap e-consent framework allows you to password protect e-consent forms for added security and identity verification.



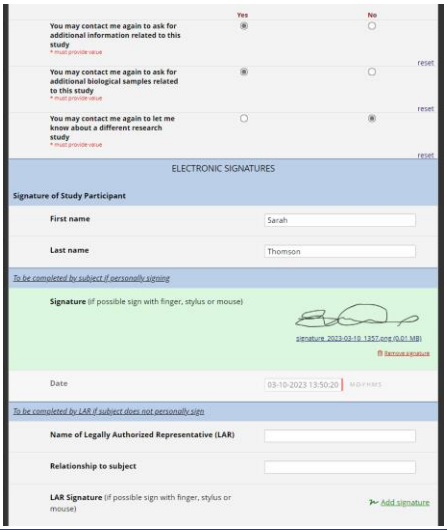
E-Consent Platform Examples - REDCap



Multi-language management in REDCap → integrate multiple languages/e-consent translations and toggle between languages with ease.

Branching logic makes short form e-consenting and meeting necessary requirements simple, no guesswork!

E-Consent Platform Examples - REDCap

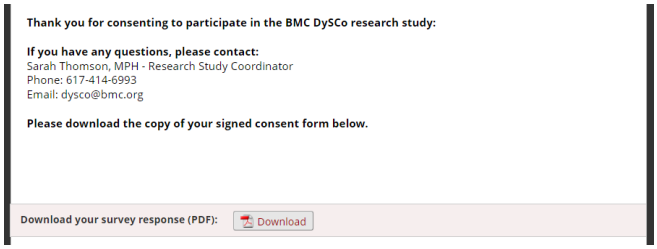


Multiple choice options in lieu of initialing or checking boxes next to preferences in the paper consent form.

Electronic signature fields, automatic tracking of date and time.

Accommodating multiple consent scenarios on one form (self-signing, LAR signing on your behalf, etc.)

E-Consent Platform Examples - REDCap



Easy access to consent documentation.

Download a copy of your signed e-consent form in your preferred language with a single click.

Chat storm!

What are some benefits of using econsent? What are some motivators to use econsent?

E-consent Benefits and Advantages

For research **participants**. . .

- Research accessibility
- Flexibility
- Comprehension and retention
- Cost-effective

Figure 1 Potential Components of eConsent

E-consent Benefits and Advantages

For research **staff, sponsors, IRBs**. . .

- Participant accessibility
- Improved version control
- Lower administrative burden
- Easier auditing

Chat storm!

What are some of the challenges you've faced in the e-consent process, or potential challenges that come from using e-consent?

E-consent Challenges - Accessibility (again!)

- Equity issues
  - Who does e-consent give us **access to**?
  - Who are we **alienating**? Who are **missing entirely**?
- Digital literacy
  - Age/illness and e-literacy
- Consistent technology access
  - Internet connectivity/stable wifi
  - Smartphone/computer access
  - Phone service

E-consent Challenges: Privacy and Data Security

- Concerns about privacy in the digital environment
  - General concerns about online security
- Confidentiality of personal information
- Ability to be in a private location
  - Possibility of coercion from family
  - Possibility of concern of sensitive topics being overheard

E-consent Challenges - Communication, Comprehension and Engagement

- How do we…
  - Maintain communication during remote consent?
  - Ensure that potential participants comprehend study requirements, risks, etc.?
  - Ensure that potential participants are engaged?

In a nutshell: **how do we guarantee truly informed consent?**

E-consent Challenges - Ethics

- Is eConsent ethical?
  - Purpose of INFORMED consent…
  - Concern that more online consent will lower standards of traditional consent
- Consent to download software, or start a subscription
  - “Terms and conditions”
- Consent length
  - Traditional vs online; duration of time spent in the consent process
- Can be amended by clear regulations and creative adjustments

Breakout room: Case Study

You are preparing for a research study examining the neurology of rural farmers who abuse opioids. Screening for the study can be completed remotely. The study includes a one-time in-office visit consisting of a staff administered substance use disorder diagnostic assessment, EEG, MRI, and urine drug screen, and is expected to last approximately 4 hours. In order to participate, the individual must currently be abusing opioids, must be able to complete study procedures, and must live at least 20 miles from an urban area. Assume that consent and study procedures cannot be done on the same day (staffing/participant schedules/etc).

Now that we've considered the benefits and challenges of e-consent:

- What are some of the considerations you should account for when deciding if e-consent is a good fit?
- How would you address e-consent issues (accessibility, privacy, maintaining communication, increasing understanding/engagement, and ethics) when implementing e-consent for this study?
- What are some other ways you can reach this population where they are to complete the consenting process?

Strategies for Implementation: Accessibility

- No one-size-fits all approach.
- Providing alternatives, building flexibility into protocols, and taking participant preferences into consideration.
- Making paper consents available for those who don't feel comfortable or familiar with digital platforms
    - Paper consent review in person, consent mailing and return, etc.

Strategies for Implementation: Privacy/data security

- Using HIPAA-compliant and/or encrypted software.
- Keeping study data separate from PHI and limit access.
- Being transparent about what data will be shared and how you will keep their information secure.
- Communicating the importance of reviewing consent in a distraction-free place, and ensuing the participant feels comfortable during consent (private, quiet space).

Strategies for Implementation: Communication, comprehension and engagement

- Goal → increase participant understanding and autonomy.
- Making the consent process interactive and engaging
  - Multimedia components, comprehension assessments, teach back, etc.
- Providing access to study staff contact information, and making sure that someone is available to answer participant questions (phone, video) and support them during consent process and beyond.
- Comprehension assessments!

Ethics - The Bottom Line

- Goal of the informed consent process → increasing participant understanding and autonomy.
- Utilizing a mix of the strategies and solutions previously outlined is important, and frequent check ins with participants beyond initial consent is important, especially in the electronic setting.

Population Considerations: Reflecting on our experiences

- Sarah:
  - Recruiting COVID-positive patients and healthcare workers at a safety-net hospital
  - E-consent allowed us the flexibility we needed for various recruitment methods
    - Multiple study arms (remote AND in-person e-consent)
    - Accommodating multiple translated and short form consents
    - Limiting paper in COVID-positive space
- Kristen:
  - Recruiting veterans (and partners) who received a service dog from K94W
    - E-consent offered the ability to look at this specific, scattered population
    - Concerns with electronic privacy/trust formation
  - Recruiting couples for AUD treatment study
    - Only remote after COVID
    - Expanded recruitment to other parts of the state
    - Concerns with confidentiality/privacy

Conclusions/Summary

- No matter the consent modality (paper, e-consent, in-person, remote), protecting participants' rights and welfare is the number one priority
- As e-consent becomes more popular and widespread (decentralized trials, increasing representation, technological innovations) there are many considerations to keep in mind
- Flexibility is key - no one-size-fits-all approach
  - So many ways to design e-consent forms for your research - get creative, keep your target audience in mind and stay flexible
- Keep institutional requirements and guidance in mind!

Resources

Institution	Resources
University of Florida	Building e-Consents in REDCap & IRB Guidance on e-Consent ***REDCap** is **required** for interventional study e-consents; **Qualtrics** may be used for survey-style exempt research
Boston University Medical Campus/ Boston Medical Center	CRRO website has all information on e-consent tools and guidance. *If you are conducting a drug or device study and using REDCap for data collection, including e-consent, you must comply with FDA 21 CFR Part 11 requirements for electronic records and signatures. Complete the BU REDCap Part 11 Request Form to get started.
Medical University of South Carolina	SCTR Remote & Virtual Trials Resources links: • MUSC eConsent Project Template - REDCap • Doxy.me Guidance • MUSC Policy on Informed Consent • Electronic Consent Guidance *MUSC uses REDCap and Doxy.me platforms for e-consent.
University of Vermont	UVM IRB Policies on Electronic Consent & UVM REDCap project development resources

FDA Guidance: Use of Electronic Informed Consent Questions and Answers (fda.gov)
OHRP: OHRP: Use of eConsent in Human Subjects Research Presentation

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Questions?