UNIVERSITY of MARYLAND
SCHOOL OF NURSING

eConsent in Human Subjects Research
What is it and what is it not?

Casey Jackson, MS, CCRP
Research Quality Manager
University of Maryland, Baltimore
School of Nursing

Disclaimer

It is up to the IRB, not the researcher, to approve use of electronic consent (eConsent) in human subjects research.

This presentation highlights the definition of eConsent and briefly mentions the use of two platforms (REDCap and DocuSign) for obtaining an electronic signature. This presentation is not an endorsement of either platform, nor the explicit use of eConsent in all research. Decisions as to the use of eConsent and what electronic signature capture platform is used depends on the type of study, the recruitment plan, and the approval of the IRB.

Goals

By the end of this seminar you should have an increased knowledge of:

1) eConsent misconceptions
2) The federal regulations and local policies concerning electronic signatures and documentation of consent in research
3) GCP, compliance, and IRB application considerations for eConsent use

Quiz: True or False?

eConsent is a waiver of documentation of consent

-False

eConsent is appropriate for minimal risk exempt studies

-False

You can use any electronic platform to capture an eConsent signature

-False

eConsent removes the need for delegating a study team member to consenting procedures

- BIG False! 45 CFR 46.116

eConsent at UMB- what is it?

- Is an electronic, verified alternative to the hand-written signature on a consent form document
- May be applied to **non-exempt human subjects' research studies** (MR or GTMR)
- Platform for obtaining electronic signature must be approved by UMB
- Plan involving eConsent must be approved by UMB IRB

eConsent at UMB- what is expected?

Written Documentation of Consent UMB HRPO SOP HRP-091

"5.4 Electronic consent

- Electronic consent document includes all elements in HRP 311 Criteria for Approval and Additional Considerations Section 8-Elements of Consent Disclosure
- The date of the electronic signature will be captured (N/A if waiver of documentation of consent is requested and justified).
- Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
- See HRP 311 Criteria for Approval and Additional Considerations for further informed consent process requirements for electronic consent."

UMB HRP 311- Worksheet

Electronic Consent

1 You indicated that consent will be obtained electronically. Please confirm the following:

- Electronic consent document includes all elements of informed consent disclosure.
- The date of the electronic signature will be captured (N/A if waiver of documentation of consent is requested).
- Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
- Electronic consent process includes age appropriate materials to facilitate comprehension.
- Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
- Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
- Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.
- Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
- The informed consent process outlines in detail how any included documents will be utilized.
- Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.
- For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identity and assent when the child initially presents to the investigator (N/A if the research is not an FDA-Regulated Clinical Trial).

Outside UMB eConsent Expectations

DHHS Regulations: (45 CFR § 46.117): Documentation of informed consent

FDA Regulations (21 CFR § 11): FDA Guidance on 21CFR11

Departmental policies?

Sponsor policies?

Electronic Signature- what is it?

Definition varies according to organization:

"OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted." **–DHHS Q&A**

"IRBs, investigators, and sponsors should consider…how the electronic signature is created… [They] may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements contained in 21 CFR part 11" **–FDA/DHHS Q&A**

"An e-signature means any electronic sound, symbol, or process, which is attached to or logically associated with a contract or other document, and which is executed or adopted by a person with the intent to sign that contract or document." **–UMB VI-99.04(A)**

UMB Policy IV-99.04(A)

Policy Regarding Electronic Signatures

"An e-signature on behalf of UMB is only valid if: it is executed by an individual with the intent and authority to sign on behalf of UMB and to bind UMB; it is unique to the person using it; it is verifiable; the verification information is retrievable and auditable; and the use of the e-signature is under the sole control of the authorized signatory (or designee identified in writing by the authorized signatory)"

UMB Policy IV-99.01(A)

Policy Regarding Ownership, Management, and Sharing of Research Data

V. APPROVED METHODS FOR ARCHIVING RESEARCH DATA

1. Requirements for recording and storing Research Data will vary by discipline. The PI should adhere to guidance provided by funding bodies, professional guidance where available, any principles set out at the School level, as well as policies endorsed or adopted by CITS.
2. Research Data should be stored using a method that permits a complete retrospective audit, if necessary. Unless ethical/professional /local or funding body guidance requires otherwise, Research Data should be archived in a durable form and in a secure location that is immune to subsequent tampering and falsification.

eConsent- what is it not?

Electronic consent is **not**:

- a short form consent (still need UMB template consent)
- a waiver of documentation of consent (not verbal!)
- meant for exempt research
- a replacement for the consent process
- a replacement for a study team member

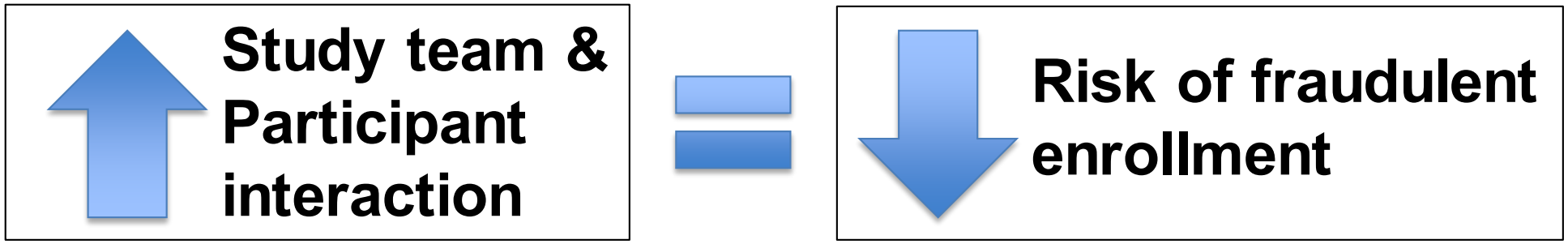
eConsent- when to use it?

- When paper option is not feasible
- When the use of it is justified
- When use of it does not take away from the consent process
- If it potentially improves the consent process

eConsent- when NOT to use it?

- Participant pool has limited electronic resources/skill (elderly, economically disadvantaged, etc.)
- In lieu of low resources
- Without IRB approval
- Studies with high risk for fraudulent enrollment

eConsent is NOT a recruitment plan



Incentives + social media recruitment + low subject interaction= **very risky**

What is your enrollment monitoring plan?

Threats of Bots and Other Bad Actors to Data Quality Following Research Participant Recruitment Through Social Media: Cross-Sectional Questionnaire

Rachel Pozzar [1]; Marilyn J Hammer [1]; Meghan Underhill-Blazey [1,2]; Alexi A Wright [3]; James A Tulsky [4]; Fangxin Hong [5]; Daniel A Gundersen [6]; Donna L Berry [1,7]

271 surveys completed in 7 hours

94.5 % of responses fraudulent

86.7% of responses inconsistently verified

16.2% bot automated

https://www.jmir.org/2020/10/e23021/

THE VERGE

SCIENCE

A TEENAGER ON TIKTOK DISRUPTED THOUSANDS OF SCIENTIFIC STUDIES WITH A SINGLE VIDEO

Researchers were caught by surprise after a short video sent a flood of new users to a survey platform

By Rafi Letzter | Sep 24, 2021, 9:00am EDT

https://www.theverge.com/2021/9/24/22688278/tiktok-science-study-survey-prolific

eConsent does NOT remove eligibility assessment

Stanford MEDICINE | Department of Psychiatry and Behavioral Sciences

Rodriguez | LAB
Translational Therapeutics

Online Paid Research Study

Understanding Suicide Attempt Risk Factors

Contribute to reducing suicide by volunteering in a Stanford University research study

Contact us for a confidential eligibility interview:

itsastudy@stanford.edu

(650) 497-2577

Eligible individuals will be invited to participate in online assessments and two follow-up phone calls. Participants will receive $100 after completing all study visits.

For questions regarding participants' rights contact 1 (800) 680-2906.

National Suicide Prevention Lifeline: 1-800-273-TALK (8255) or Text "HOME" to 741741
If you are in crisis, call a provider or 911 or visit your nearest emergency room.

RESEARCH STUDY ON DATING EXPERIENCES OF NON-HETEROSEXUAL INDIVIDUALS

Researchers at the University of Tennessee - Knoxville are conducting a study to look at positive and stressful experiences in intimate non-heterosexual relationships.

We are looking for individuals who
-Are between the ages of 18-25
-Drink alcohol
-Are currently in a dating relationship

Individuals of all gender identities and non-heterosexual sexual orientations are eligible to participate

IF INTERESTED, TAKE A PICTURE OF THE QR CODE ON YOUR SMART PHONE AND COMPLETE THE SURVEY TO SEE IF YOU ARE ELIGIBLE

You can also send an email to utk.relationship.study@gmail.com or call us at (865) 974-3489

Is eConsent risky?

- Potential for fraudulent enrollment depending on recruitment strategy
- Vulnerable populations
- Potential pressure to agree
- In person vs remote
- Device/platform may adversely affect comprehension

Is eConsent beneficial?

- May improve consent process
- Comprehension
- Engagement/outreach/access
- Documentation/QA/automated reporting
- Productivity

CICERO- UMB IRB application

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [x] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [x] Written Consent Form
- [x] Electronic Consent

CICERO- IRB application considerations

2 * Describe the Informed Consent process in detail: HELP

- Process starts at recruitment and goes until the end of participation
- Pilot your eConsent process many times before implementing
- What about a copy of the consent?

4 * Describe who will obtain Informed Consent:

- NOT the eSignature platform!

CICERO- IRB application considerations

6 * Describe the setting for consent:

DETAILS!

7 * Describe the provisions for assessing participant understanding:

- **Talk back method? Quizzes?**

8 * Describe the consideration for ongoing consent:

- **Consent process does not end with signing of eConsent!**

CICERO- IRB application

- Upload full consent form draft here to be stamped
- Must use the HRPO consent form template

GCP Considerations

Reporting/Validation

Logs/Monitoring

Documentation/Recording

Revisions

DocuSign

- Use/look is fixed
- Research team explicitly involved in providing access to the consent via email “Template Option”
- “Powerform option” not appropriate for research; not GCP compliant
- Consent copy automatically sent to participant and research team via email through DocuSign
- Consent process described in CICERO must also include DocuSign process
- FDA regulated studies require 21CFR11 module of DocuSign $

REDCap

- Use/look of consent depends on how REDCap is built
- Access to consent may be research team or participant driven
- Consent process described in CICERO must include what you have built
- Need to build in mechanism to provide consent copy to participants
- Build for 21CFR11 compliance if FDA regulated

UMB HRPO Website

OHRP Webinar on e-Consent

-Highlights need for participant driven navigation and pace through e-consent process

-Notes lack of standardization around e-consent

-Outlines the benefits and concerns around e-consenting in person or remotely

-Promotes use of quizzes in the consent process (assess understanding)

-Discusses digital divide as a barrier to accessibility

Questions?

Casey.Jackson@umaryland.edu

UMB IRB: hrpo@umaryland.edu