Remote and E-consent
(including REDCap)

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Objectives

- Explain Remote and e-consent and when the two overlap
- Show the options for developing e-consent using REDCap and DocuSign
- Describe important IRB issues in regards to remote and e-consent

“When it comes to experimentation in man… what is sought is ‘informed’ or ‘valid’ consent; it is on this rock that many if not most of the ethical problems come to grief.”

H. Beecher in *Research and the Individual*, c. 1970, p. 19

Goals of Informed Consent in Research

Ensure that research participants…

- Have the necessary info (i.e. required elements)
- Understand the necessary info
  - Form: complete information; readability
  - Process: constructive dialog → assessment of understanding → constructive dialog, and-so-on…. → signing/documenting

… to make an *informed decision* regarding participating in a research study.

…to make the decision that is right for the subject….

Remote Consent

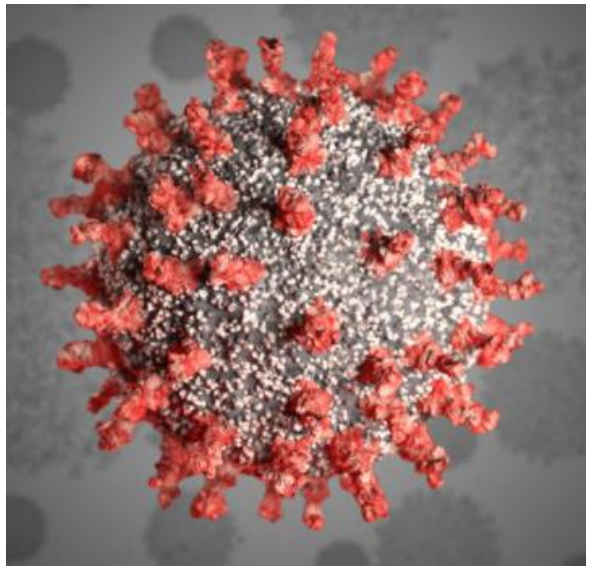
- Not in the same physical location
  - Not able to sign the same hardcopy consent form
  - Not able to use the same device for e-consent
- Remote consent can be a hardcopy OR e-consent process

Electronic informed consent…E-Consent

- Use of electronic systems and processes
- Convey information about the study
- Obtain and document informed consent
  - E-platform captures valid e-signature

- E-consent process can be in-person or remote
  - In-person: consent on a tablet; passed back and forth to sign
  - Remote: Link to e-consent sent (email etc.) to subject who signs electronically; investigator then signs electronically

COVID-19 – Necessitated rapid changes



- Remote and e-consent were used prior to COVID-19
- New processes to conduct remote consent were needed for research with COVID+ subjects/LARs
  - Limit potential for viral transmission and use of PPE
  - Remote consent with witness
- New processes needed for research that could move to remote enrollment and/or follow-ups
- Increased openness to adopting e-consent process
  - IRB, study teams, subjects, etc.

Contains Nonbinding Recommendations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

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Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Updated on December 4, 2020

Remote Consent: How to conduct consent process?

Remote process using “hardcopy” forms

Consent of COVID inpatient (able to consent)

- Consent discussion by phone or video-conference
- COVID+ subject signs his form in hospital room; keeps it
- **Witness** signs a different copy *on behalf of and as directed by subject*
- Investigator signs form after witness; this version kept for records

Consent of LAR who is not in the hospital w/subject (Subject is not able to consent for herself)

- Consent form emailed to LAR
- Consent discussion by phone or video-conference
- LAR prints form, signs it, scans it, emails it back
- Investigator signs form after received from LAR; this version kept for records

Remote Consent: How to conduct consent process?

Remote process using e-consent

- Consent discussion by phone or video-conference
- No witness required to sign on behalf of subject
  (May need witness for other reasons)
- Documentation via electronic signature
  - Subject then investigator sign electronically

Signing the e-consent form

- Valid e-signature
- In-person (same location)
  - The investigator and subject review the same document
  - Investigator can personally verify identity of the subject and see who is signing the consent
- Remote
  - Subject not in same location as investigator
    Investigator may not be able to see who is signing the consent
  - Process should include a method to ensure that the person electronically signing the consent is the subject who will be participating in the study (or LAR)

The regs

- FDA: 21 CFR part 50: Informed Consent
  21 CFR part 56: IRB Review/functions/operations
  21 CFR part 11: Requirements for electronic records/electronic signatures
- HHS: 45 CFR, part 46: Protection of Human Subjects
  - Harmonized with 21 CFR 50 and 56, above, NOT part 11

Type of research	Regs that apply
Research testing an FDA-regulated product	21 CFR parts 50, 56, and 11
Research testing an FDA-regulated product AND that gets HHS funding	21 CFR parts 50, 56, and 11 *AND* 45 CFR, part 46
Research not testing a drug/device/biologic	45 CFR part 46 (*not* 21 CFR parts 11, 50, 56)

Platforms for e-consent

- Sponsor-provided platform

- For investigator-initiated studies

  DocuSign *(BU Med Campus/BMC)*
  - FDA-regulated research (part 11 compliant)
  - In-patient drug trials with COVID+ subjects

  REDCap e-consent platform
  - Tools to obtain and store consent
  - FDA-regulated research: must be validated Part 11 compliant at the institution/ site
  - Currently there is a BU Medical Campus/BMC working group that is working towards the goal of our “instance” of REDCap meeting part 11 requirements

Considerations

- E-consent requires technology and familiarity with technology that not all potential subjects have access to
- Research level of risk and other factors may dictate what e and remote consent options are appropriate
- Loss/limited available cues that we would normally have with an in-person interaction
- Consent of LARs for COVID or other inpatients is different due to LAR not being able to be at bedside
- Details related to FDA regulated research – validation of the subject's identification
- The use of these processes for so many research studies is new, and will likely evolve with experience (as will guidance for these processes)
- Ultimately the IRB is evaluating the compliance with regulations regarding informed consent, and if the process and documentation are appropriate and adequate

New Guidance

- Using E-consent at BMC and BU Medical Campus
- Guidance on Developing REDCap E-Consent: Non-Exempt Research Requiring Signatures
- Guidance on Developing REDCap E-Consent: Minimal risk or Exempt Research Not Requiring a Signature and Exempt Research that include HIPAA Authorization

http://www.bumc.bu.edu/crro/tools/e-consent-tools-and-guidance/