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Current as of 02 May 2018

Agenda

- Background
- Experience to Date
- Patient Experience
- Health Authority, Ethics and Laws
- What we need from you?

Myths of eConsent

1. It is simply a paper document transcribed onto a mobile device

2. It is very difficult to set up and Implement

3. Ethics Committees will not approved electronic consent

1. The sponsor provides no support in relation to the set up of eConsent

Truths of eConsent

It contains helpful information that assists the patients in understanding the information in the trial;

1. Comments or flags – including prompts to go back to that information
2. Call out boxes
3. Pictures and Diagrams
4. Audio
5. Digital Glossary, underlined words
6. Reports, data/time, Version control
7. Digital eSignature or sign paper

Truths of eConsent

8. Translations are easier
9. The patient can still receive a paper copy of the ICF to go through at home before they sign the eConsent
10. eConsent is not mandatory
11. Has been implemented in at least 7 countries now
12. Digital technology that enhances patient comprehension of the ICF and utilizes multi media components, e.g. video, audio and hyperlinked glossary terms.

eConsent – Signature Modalities

eSignature

- The subjects reads the eICF on the e-Tablet device
- E-signatures are collected on the e-Tablet device

Print-to-sign

- The subjects reads the eICF on the e-Tablet device
- Signatures are collected on paper

Example of a Submission for eConsent

1. HREC has approved the e-consent for a study
2. eConsent was submitted to the ethics committee post initial approval as an amendment.
3. The paper PICF was submitted and approved first
4. The process was smooth
5. A submission package was put together with screen shots of the eConsent process.

** 2 other sites initially planned to participate in eConsent

Example of a Submission for eConsent

1. Has been submitted to HREC
2. Waiting for comments back from HREC
3. Vendor puts together a submission package
4. 2nd site will be submitting shortly. If approved, it will then go to Institution for institutional approval

** 2 other sites that were initially interested but dropped out.
Reasons;

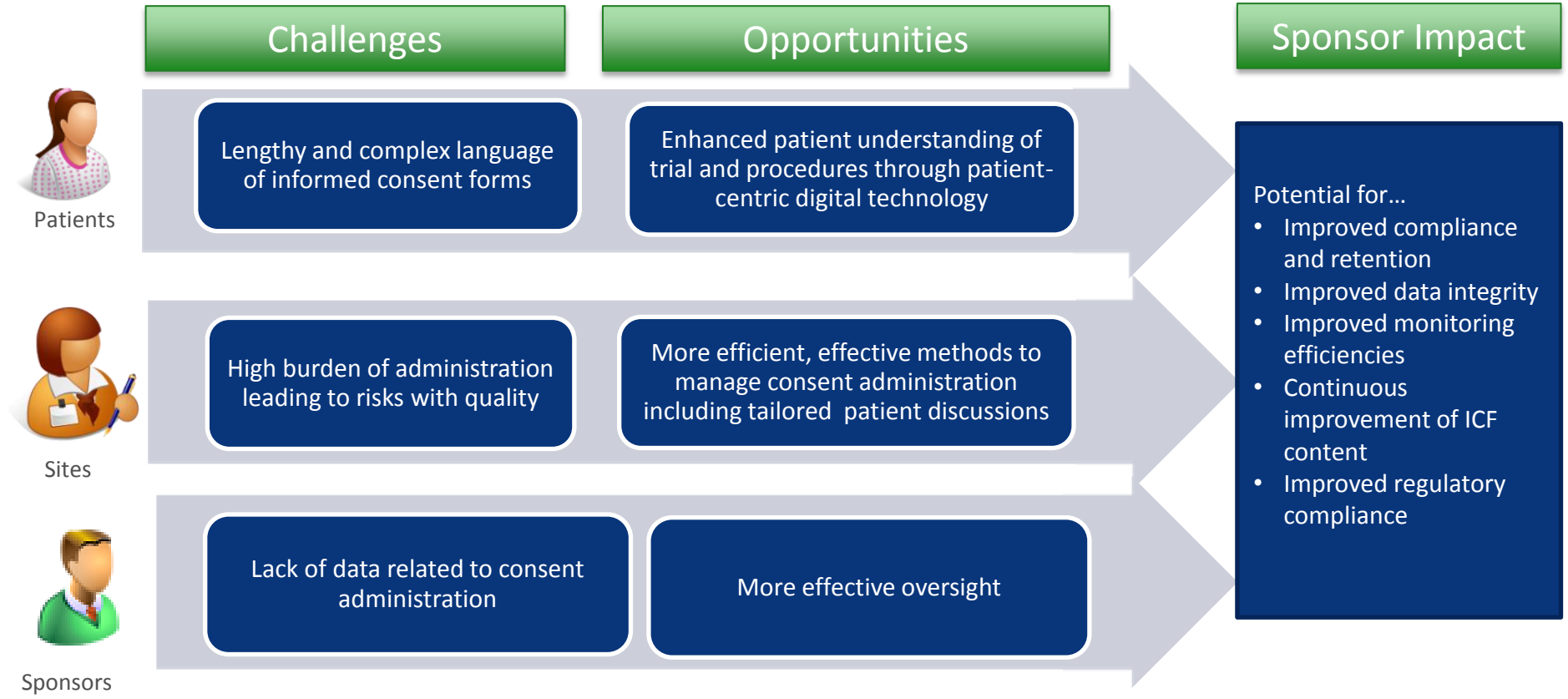
1. Poor WIFI (and broadband) connection via their ePRO device
2. Site just lost interest

Feedback


"More responsive than a paper document. Informative"
"Easy to navigate"
"I like the ability in the consent to go back to different sections"
"This was easier and certainly more thorough"

Key Stakeholder Benefits for eConsent Adoption

- **eConsent will support the drive for more patient-centric and innovative clinical trials**



HA Feedback Overview

Support

- **Information Provision**
- Enhance patient-site discussion to better inform patients.
- Particular value for paediatric populations.
- Paper option should always be available.

Concerns

- **eSignature & Data**
- Data protection, storage & archive.
- Process owned by site.
- Transparency with HAs, even if EC/IRB approves Informed Consent Form (ICF).
- Consider local requirements.

HA Feedback used to shape deliverables & rollout

FDA and eConsent

December 2017 , the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) released joint guidance about the use of electronic Informed Consent.

Ensuring Legal/Regulatory Requirements are Adhered To

US Requirements per the eConsent Final Guidance [a]	
Human Research Protections	21 CFR Part 46 +21 CFR Part 50 (IC)
Good Clinical Practice	ICH E6(R2) + GCP guidance
Privacy[b]	EU US Privacy Shield
Electronic Records / Security	Secure with restricted access per 21 CFR 11.10 & 11.30 Subject Information encryption
Electronic Signature	Global and National Commerce Act (eSign Act; Public law 106-229) 21 CFR Part 11 & Guidance

a. US Guidance co-authored by HHS OHRP, FDA & FDA decisions (effort lead by CDER Office of Medical Policy
b. Privacy, security and Breach Notification Rules (21 CFR parts 160 & 164) apply if covered or associated business entity under HIPAA

Australian Privacy Laws, HREC review *Case by case basis – adherence to all local laws and regulations	Privacy Principles Australian Privacy laws

How are eConsent data kept private?

This can be accomplished in a few ways;

- No patient information is stored on the tablet that is used to deliver the eConsent.
- When full e-signature is used, eConsent information can be transferred to a secure server and stored per local regulations
- Access to the eConsent application is restricted by a unique user name and password that is provided to each person at a study site and within the study team.
- Access is role based, and the accessible information will vary depending on the user's involvement with the study

What we need from you?

1. Embrace technology – Clinical Research is becoming increasingly electronic, everyone needs to be comfortable in this space. How can we help?

2. Give staff time to train in the new technologies

3. HRECs to develop clear review guidelines, checklists, and SOPs or the like

4. Do HRECs need to consider whether they need an IT expert on their committees or can they access an IT expert for advice if needed?

What we need from you?

5. Do you have someone at your site that the Site staff can contact for IT issues – we will provide support from our end

6. Items that can present problems;

- Firewalls
- Wireless access (if using tablets)
- Lack of IT knowledge
- Fear of technology
- Tablet issue vs Log on via a web site

7. Is there someone we can work with to develop NMA guidelines for eConsent review and approval for HRECs and RGOs?