Consenting Study Participants in the 21st Century

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Outline

I. Background
   • Purpose
   • Technology

II. Application
   • How it works (interactive example)

III. Future of eConsenting
   • Considerations for study teams
   • IRB uptake and regulation

IV. Resources for research teams
Learning Objectives

At the end of this presentation, participants will be able to:

• Understand the benefits of electronic consenting (e-consenting)
• Identify important issues when considering the use of e-consenting
• Describe the potential challenges in e-consenting for both study participants and the research team
Section 1:
Background
Informed consent & assent in biomedical research

The principle of consent is closely related to the principles of:

I. Autonomy,
II. Self-determination and
III. The affirmation of human rights and respect for human dignity.

Components of informed consent

Adequate informed consent consists of three required elements: (Appelbaum and Roth 1982; Christensen et al. 1995; Faden & Beauchamp, 1986)

1. Full information;
2. Voluntary participation; and
3. Capacity to make a decision
**Traditional consent process** (FDA, 1980; HHS, 1991; CIOMS WHO, 2002)

Begins at first contact…

- **Environment**
  - private, confidential, and “safe” setting

- **Assessment of Capacity to Consent**
  - based upon the likely degree of cognitive or decisional impairment

- **Presentation of the Elements of Informed Consent**
  - Facilitate dialogue, sequential, repetitive

- **Adequate Time & Use of a Delayed Consent Procedure**

- **Assessment of the Participant’s Comprehension**

- **Documentation of Informed Consent**
Potential challenges with the Informed Consent Process

• **Lack of standardization** (Bhutta, 2004; Joffe et al., 2001; Paasche-Orlow, Taylor, & Brancati, 2003; Sieber, Plattner, & Rubin, 2002)
  - Pros and cons to standardizing forms and procedures (Lo & Barnes, 2011; Sung et al., 2003)

• **Time-consuming** – May deter individuals from participating in research (participant fatigue; contributes to study team fatigue) (Bhutta, 2004; Sung et al., 2003)

• **Resource intensive** – Study team personnel must be specially trained in order to deliver informed consent (Paris et al., 2010)

• **Communication is at times inadequate/unclear** – Individuals may not understand what they are consenting to do as a potential participant in the study (Sieber, Plattner, & Rubin, 2002; Paris et al., 2010; Joffe et al., 2001)
“Greater application of standardized electronic record keeping appears to be a logical means to increase efficiency.”

Findings from numerous studies and a few meta-analyses confirm that interactive, multimedia-assisted ICFs:

- improve participant understanding,
- reduce literacy-related barriers,
- increase participant & researcher satisfaction with the consent process,
- result in longer recall times of comprehension-related items, and
- simplify the process of declining to continue

Afolabi et al., 2014; Flory & Emmanuel, 2004; Jimison, Sher, Appleyard, & LeVernois, 1998; Mahnke et al., 2014; Nishimura et al., 2013
## Electronic ("e") Consenting Technologies

<table>
<thead>
<tr>
<th>Feature</th>
<th>Web-based</th>
<th>Computerized</th>
<th>Tablet-based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic record</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Response validation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Researcher guided</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Standardized delivery</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pictoral explanation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Audio/video enhanced</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Literacy independent</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Offline</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Self-paced; flexible</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Interactive (touch screen)</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>eSignature</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
CTSA spearheaded an interdisciplinary effort to develop and evaluate eConsent technologies
Comparing eConsents to paper consents

Rowbotham, Astin, Greene, & Cummings (2013) investigated subject comprehension, delayed recall, and ratings of user acceptability of a paper-delivered and iPad-elicited informed consent.
Rowbotham et al. (2013)

Part I. Clinical researcher population

Group 1. n= 14 clinical research professionals

- Paper Consent (n=7)
  - chemotherapy
  - neuropathy
  - clinical research study

- iPad Consent (n=7)
  - chemotherapy
  - neuropathy
  - clinical research study

18-36 hrs. later

Online survey (delayed recall, included questions about the user experience, and free text space for comments).

Part II. Out patient clinic population

Group 2. n= 55 out patients

- Paper Consent (n=27)
  - chemotherapy
  - neuropathy
  - clinical research study

- iPad Consent (n=28)
  - chemotherapy
  - neuropathy
  - clinical research study

18-36 hrs. later

Online survey (delayed recall, included questions about the user experience, and free text space for comments).
Table 1. Post-review online survey test question results.

<table>
<thead>
<tr>
<th>Question</th>
<th>group1 iPad</th>
<th>group 1 Paper</th>
<th>group 2 iPad</th>
<th>group 2 Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 (Reason for study) *</td>
<td>88</td>
<td>67</td>
<td>69</td>
<td>72</td>
</tr>
<tr>
<td>Q2 (Who to call if injured)</td>
<td>100</td>
<td>83</td>
<td>89</td>
<td>72</td>
</tr>
<tr>
<td>Q3 (Who to call if questions)</td>
<td>38</td>
<td>33</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Q4 (Continue with normal treatments) *</td>
<td>75</td>
<td>33</td>
<td>89</td>
<td>62</td>
</tr>
<tr>
<td>Q5 (What involved in QST)</td>
<td>50</td>
<td>67</td>
<td>77</td>
<td>55</td>
</tr>
<tr>
<td>Q6 (Risks of QST) *</td>
<td>100</td>
<td>50</td>
<td>77</td>
<td>48</td>
</tr>
<tr>
<td>Q7 (If you require treatment)</td>
<td>88</td>
<td>67</td>
<td>96</td>
<td>59</td>
</tr>
<tr>
<td>Q8 (Amount of compensation) *</td>
<td>100</td>
<td>83</td>
<td>96</td>
<td>76</td>
</tr>
<tr>
<td>Q9 (Duration of Study) *</td>
<td>88</td>
<td>33</td>
<td>96</td>
<td>59</td>
</tr>
<tr>
<td>Q10 (What involved in study)</td>
<td>75</td>
<td>83</td>
<td>69</td>
<td>72</td>
</tr>
<tr>
<td>Q11 (What involved in QST)</td>
<td>38</td>
<td>0</td>
<td>42</td>
<td>21</td>
</tr>
<tr>
<td>Q12 (Free to stop participating any time)</td>
<td>88</td>
<td>83</td>
<td>85</td>
<td>86</td>
</tr>
</tbody>
</table>

**OVERALL PERCENT CORRECT**

- group 1 iPad: 77%
- group 1 Paper: 57%
- group 2 iPad: 75%
- group 2 Paper: 58%
Rowbotham et al. (2013)

Among both research professionals and patients, next-day comprehension was better in participants randomized to the interactive iPad consent form.

The iPad participants spent more time with the device, but the amount of time spent reviewing the actual consent document was actually shorter (13 minutes for paper, 11.4 minutes on the iPad).
Section 3: Challenges & Limitations
Considerations for study teams:

Higher up-front cost to develop eConsent;

Time required to develop and test eConsent delivery, storage, and retrieval;

Additional safeguarding may be necessary when using an eConsent with vulnerable populations; and

Training needs of study team members
### Regulatory best practices

<table>
<thead>
<tr>
<th>Regulatory Requirement</th>
<th>Paper-based forms</th>
<th>eConsent forms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Signature validation</strong></td>
<td>Study team member certifies each signature line at the time consent is obtained</td>
<td>Signature line may not be edited; study team member certifies (by signature) content is present and functional</td>
</tr>
<tr>
<td><strong>Safe Storage</strong></td>
<td>Forms should be stored under double lock and key; accessible by specially authorized personnel.</td>
<td>AES encryption, using either 128- or 256-bit keys; storage on a secured server; offsite backup for disaster recovery</td>
</tr>
<tr>
<td><strong>Participant access to form</strong></td>
<td>Hard copy provided to participant</td>
<td>Hard copy and access to interactive content</td>
</tr>
<tr>
<td><strong>Contact information</strong></td>
<td>Instructions enumerated on hard copy provided to participant</td>
<td>Contact information is provided in hard copy and via interactive content</td>
</tr>
<tr>
<td><strong>IRB-maintains approved version</strong></td>
<td>IRB maintains record of ICF (e.g. uploaded to database; scanned; etc.)</td>
<td>IRB maintains record of technology used to access form</td>
</tr>
</tbody>
</table>
Section 4:
Resources for study teams
## Resources for study teams

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HealthIT.gov</td>
<td>eConsent Toolkit that provides samples of the tools, resources, and educational materials that were used in the Office of the National Coordinator for Health Information Technology’s eConsent Trial Project</td>
</tr>
<tr>
<td>Survey Gizmo</td>
<td>HIPAA-compliant survey software used to build example</td>
</tr>
<tr>
<td>Sample Video Transcript</td>
<td>Fully mapped audio/video transcript for an eConsent used in SBS research - <em>produced by Duke Clinical Research Institute (DCRI)</em></td>
</tr>
<tr>
<td>Online Webinar</td>
<td>Addresses electronic technologies for obtaining consent, facilitating consent, storing study data, and monitoring study data – <em>produced by Quorum</em></td>
</tr>
</tbody>
</table>
Resources for study teams

healthIT.gov eConsent Toolkit

- The eConsent Toolkit provides samples of the tools, resources, and educational materials for national eHIE project.

PDFs are embedded in text
Resources for study teams

**Survey Gizmo**

Highly-learnable interface; extensive features; customizable; exports to SPSS
Resources for study teams

**Video Transcript**

**Calerie Study**

Multimedia and presenter content is fully scripted
Resources for study teams

YouTube link to hour-long webinar provided in table (Slide)
Contact Information

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