Exploring eConsent
An IRB’s Perspective on eConsent Technologies and Human Subject Protection
April 22, 2015

Presented by:
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About Schulman Associates IRB

- Established in 1983
- Superior audit history with FDA—five consecutive audits with no findings
- 21 CFR Part 11 compliant electronic systems
- Compliant with FDA, OHRP and Health Canada requirements
- Full board meetings five days a week
- Dedicated daily expedited review of qualifying minimal risk protocols
About Schulman Associates IRB

- Review outcome provided within **one business day** of new study review
- **One business day** turnaround for complete new site submissions
- **Phase I Board** with streamlined processes tailored to Phase I timelines
- **Oncology Review Board** for all phases of oncology research
- Customized services for **institutions**
- Experienced primary points of contact for sponsors, CROs, institutions and sites
About Schulman Associates IRB

- Clinical Quality Assurance (CQA) and Human Research Protection (HRP) consulting services provided by Provision Research Compliance Services

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Research Compliance Services

www.provisionrcs.com

Provision is a joint venture between Schulman Associates IRB and Falcon Consulting Group
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http://bio-optronics.com/clinical-conductor/

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About Today’s Presenters

Adam Roth
Director of Operations

- With Schulman since 2014
- Responsible for managing board support operations, including consent development, safety reporting and study change management
- Has conducted or managed trials in all clinical phases and multiple therapeutic areas
- Over 17 years of research site, CRO and IRB experience
About Today’s Presenters

Ashley Dixon
IRB Member

- With Schulman since 2007
- IRB Member since 2009
- Project lead for Canadian Ethics Board development and implementation
- Bachelor’s Degree in Theology from Apostolic Bible Institute
Use of Electronic Informed Consent in Clinical Investigations, Questions and Answers


- Recommendations on the use of electronic media and processes to obtain informed consent for FDA-regulated research
- Comments due by May 8, 2015
Objectives

- Define key individual features and capabilities of electronic consent
- Discuss the ways each individual feature may improve subject protections
- Explain methods by which an IRB might review eConsent technology
### Purpose of Informed Consent

#### Intention
- Provide subjects with sufficiently detailed information on the study so that they can make an informed, voluntary and rational decision to participate. This includes:
  - Purpose of the study
  - Procedures/duration
  - Right to decline or withdraw
  - Risks
  - Benefits
  - Compensation
  - Resources for questions

#### Limitations
- Subject comprehension
- Readability
eConsent Features
eConsent Features

- Introductory video
  - Engaging presentation of informed consent process.
  - Consistent across staff and sites

- Electronic signature
  - 21 CFR Part 11
  - Time and date stamp

- Imbedded multimedia
  - Procedure videos
  - Images
  - Voice-overs
eConsent Features

- Subject questions
  - Enhanced environment for asking questions
  - Log in real-time
  - Definitions

- Confirmation of understanding
  - Sectional subject attestation
  - Comprehension quizzes/self-assessment
eConsent Features

- **Webcam**
  - Confirm attention to IC
  - Consent recording
  - Remote consenting

- **Metrics**
  - Time of IC review
  - Subject time per section of IC
  - Data regarding terms or sections of the IC that are problematic for subjects
  - Data regarding the use of multi-media within the document

- All of these lead to enhanced IC comprehension
eConsent Benefits
Benefits to Study Participants

- Enhanced understanding of the research
  - Online test of IC comprehension 1 day after consent process
    - eConsent users had higher scores than standard paper ICs: eConsent - 75%, paper IC - 58%
  - Increase in time spent reviewing IC
    - eConsent users spent more time reviewing the IC (22.7 min) vs. paper-based IC (13.2 min)

- Enhanced opportunity to ask questions
  - eConsent users reported more questions (5.7) vs. paper based ICs (4.2)

Sources:
Benefits to Study Participants

- Customizable methods of making the consent appropriate for a specific culture/population

- Metrics
  - Subject time per section of IC
  - Data regarding terms or sections of the IC that are problematic for subjects
  - Data regarding the use of multi-media within the document

- Depending on study population, a tablet or computer delivery may be more approachable than 25 pages of black & white text
Benefits to Sites

- Enhances subject comprehension
  - Increased retention
  - Decreased protocol deviations (missed visits, dosing errors, etc.)

- Minimize regulatory inspection findings
  - Associated with failure to consent subjects with most recent informed consent
    - New subjects
    - Active subjects
  - Consent errors
  - Delegation log
  - Misplaced ICs

- Limited access to PHI
Benefits to Sites

- Manage additional information collected in IC
  - Sub-study participation
  - PCP notification
- Integration with EMR
- Real-time updates to sponsors/CROs regarding enrollment
  - Avoid reporting errors
Benefits to Sponsors/CROs

- **Metrics**
  - Site activity
  - Real-time screening data (some can integrate with CTMS/IVRS)
- Potential mechanism for remote monitoring of informed consents
- Remote control of ICs
  - Sponsor or IRB stops enrollment
Adoption Hurdles

- Cost
- Not appropriate for all subject populations
  - Technology savvy
- May be a challenge to manage with site specific changes (multi-site trials)
  - Interactive components
- Additional delays when an IC is revised
- Limited use for remote consenting
  - Waiver of documentation of IC
Adoption Hurdles

- BYOD = Bring Your Own Device
- Hardware considerations
  - Screen size
    - Readability/font size
    - HIPAA font size requirements (CA: 14 point font required)
  - Amount of memory required to run software
  - Signature capture
    - Touchscreen
    - Typical PC or Mac
  - Smart assistant available to read consent, if required
    - Different platforms (Apple, Android, Windows, etc.)
    - Software versions
  - Security considerations
IRB Considerations
Is the study population appropriate for eConsent use?

- Studies involving the elderly
- Studies involving individuals with cognitive compromise
- Studies involving individuals who are unfamiliar with use of modern technology
Ideas for Streamlining IRB Review

Can work with IRBs to develop library of approved introductory video and imbedded materials

- Pre-negotiated content
- Proactive review of content
Make IRB aware of intent to use eConsent:

- Vendor
- Description of the process/functionality
- Description of the technology subjects will use
- Process by which a hard copy will be produced for subjects
- Documentation that electronic signature are 21 CFR Part 11 Subpart C compliant
- Privacy/security considerations
  - Where is PHI stored?
  - Access to information changes based on login
Paper informed consent submitted and approved

Storyboards and scripts submitted for review prior to production

Document changes in IC during “digitization”

Board review final subject-facing document/production
eConsent is a great innovation that will significantly improve subject comprehension and protection.

eConsent features and capabilities are pretty well developed, but eConsent use is still in its infancy.

The challenge: figuring out how to make eConsent more widely implemented.

It’s clear that we need to change the way we think about informed consent—as not just a document but as a process.

• eConsent is a great way to do this.
eConsent Vendors (Partial List)

- Enforme Interactive/Secure Consent
  - www.enforme.com

- Mytrus
  - www.mytrus.com

- Standard Register/iMedConsent
  - www.standardregister.com

- Systemedicus
  - http://systemedicus.com
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