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eConsent: Start Planning Now for the Inevitable

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DESCRIPTION

It is time for researchers and sites to begin planning for the inevitable shift to a paperless informed consent process.

TOPICS

- WHAT IS ECONSENT?
- WHY ECONSENT
- REGULATORY REQUIREMENTS
- REVIEW AND APPROVAL

On The Brink of a Revolution

The research community is on the brink of a revolution. Today, the process of enrolling trial participants and documenting informed consent involves long paper documents, multiple wet signatures, frequent revisions and long-term paper archives. Electronic systems are quickly replacing paper processes across the medical industry, and some estimate that the paper-based informed consent process will be replaced by eConsent systems within five years. However, very few research sites are prepared for this change; a recent survey shows that only 13% of sites are even aware of eConsent.[1] It is time for researchers and sites to begin planning for the inevitable shift to a paperless informed consent process.

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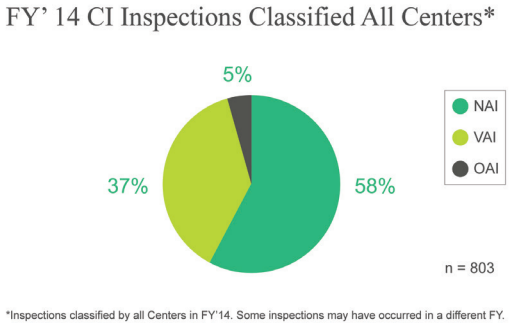
What is eConsent?

The term "eConsent" refers to technology that facilitates the electronic review and signature of consent forms. A number of eConsent tools are on the market and even more are in development. These software tools are designed in very different ways. Some eConsent software consists of an app that can be used only on certain hardware, such Apple's ResearchKit eConsent tool for the iPhone. Other eConsent software is cloud-based and can be accessed through a web portal on any device with internet access.

Similarly, a range of functionality is available in eConsent tools. Some products present a digitized version of the hard-copy consent form. Other products display additional elements, such as audio, videos, graphics, or hyperlinks to convey information about the trial. eConsent tools can be used at a research site to facilitate the in-person consent process; eConsent tools also can be used to obtain the consent of remote parties or to support on-line studies.

Why eConsent?

The paper-based process of obtaining informed consent is fraught with risk of error. Every year, the Food and Drug Administration (FDA) reports metrics from its Bioresearch Monitoring (BIMO) inspections from the previous year. In 2014, BIMO inspected 803 Clinical Investigators. These inspections resulted in 337 VAI (voluntary action indicated) and OAI (official action indicated) letters.[2] Among the top six findings in these letters was inadequate participant protection, which includes informed consent issues.[3] Consenting errors ranged from failure to obtain consent to use of an incorrect version of the consent form to inadequate consent documentation to missing required consent form elements.



Graphic adapted from FDA Bioresearch Monitoring (BIMO) Metrics –FY'14, slide 3

The findings from 2014 echo the findings from the eight years of preceding inspection metrics published by BIMO; namely, informed consent issues remain among the top failures at clinical sites.[4]

Electronic tools for delivering informed consent can help reduce, if not eliminate, such errors. Most electronic eConsent tools allow sites and participants to access only the current approved version of a consent form, which helps ensure that participants are consented on the appropriate version. Some tools also automatically alert site personnel if participants must be reconsented on a revised consent form. Many tools provide alerts if the participant or study staff have failed to apply the necessary signatures or initials to the consent document. This type of version control is especially critical and helpful to research coordinators managing long term studies, studies involving numerous participants or for sites administering multiple studies.

Electronic systems also can improve the ability of site monitors and sponsors to oversee the enrollment and consenting processes. Some eConsent systems can track and display metrics relating to participant enrollment, consent form revisions, consents and re-consents. These functionalities allow sponsors, CROs and other managing entities to effectively monitor site activity in real time.

Some eConsent tools on the market include features to improve the participants' experience of the consent process, such as graphics, hyperlinks to additional information and audiovisual clips. In a recent survey[5], sites who had used eConsent systems listed the following strengths of using eConsent:

- Reduction of consenting errors;
- Elimination of a paper process;
- Easier to search for and locate consenting data;
- Quicker consent process time; and
- Automatic updates to the consent form.

Regulatory requirements

With new technology comes new compliance requirements, and eConsent is no exception. In early 2015 the FDA released a draft guidance document on electronic consent titled, *Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers*.[6] The FDA made clear that new systems that utilize electronic signatures and records must meet the electronic records and signatures requirements of 21 CFR Part 11.[7] Additionally, clinical study information, when digitized and stored, raises concerns regarding participant data security and confidentiality. The Health Insurance Portability and Accountability Act (HIPAA) protections are therefore implicated for those clinical research sites that are "covered entities" under HIPAA.[8]

Sites that are covered entities must comply with HIPAA's implementing regulations at 45 CFR 160 and 164.These regulations lay out basic requirements for the security of personal health information (PHI) stored within electronic health records, including eConsent forms. Any eConsent system must ensure that data is protected against unreasonable access, remains available for necessary access and limits that access only to key personnel.[9] These safeguards break down to administrative safeguards, physical safeguards and technical safeguards. Administrative safeguards[10] primarily consist of employee training, access, and system usage policies. Most sites that are covered entities probably will have to arrange for training and new written operating procedures in order to implement eConsent systems in compliance with HIPAA regulations.

According to the FDA's Draft Guidance, sites also are required to maintain archival records of eConsents. The Draft Guidance states:
During inspections of clinical study sites, FDA requires access to site-specific versions of eIC [electronic informed consent], materials submitted to IRBs for review and approval, all amendments to the site-specific eIC's, and all subject-specific eICs.[11]

Sites should plan to develop policies and written procedures for storing the records (and, in some cases, electronic devices) of the materials involved in the eConsent process.

Review and approval by the institutional review board

For successful implementation of an eConsent tool, each site should have a plan for communicating the proposed eConsent process to its ethics review board. In the U.S., federal regulations require that the informed consent document and

process be approved prior to use by an institutional review board (IRB).[12] These regulations apply to clinical studies conducted with federal funding or under the oversight of the FDA. International guidelines and regulations impose similar requirements.[13]

The FDA's Draft Guidance on eConsent confirms that IRBs are responsible for reviewing all facets of how eConsent tools will be used. IRBs are responsible for understanding how the consent form information will be displayed, how participants' questions during the consent process will be answered and how participants will be provided a copy of the consent form.[14] IRBs also are responsible for understanding how consent will be documented (including the use of eSignature functionality).[15] The FDA specified that IRBs are expected to be aware of site security and information and data use policies of the institution.[16]

Pursuant to the Draft Guidance, researchers and sites should be prepared to provide a range of information to the IRB. Sites also should be prepared for a multi-step IRB review process that encompasses the substance of the consent document in addition to the features of the software and the proposed consenting plan.

Conclusion

The FDA's Draft Guidance clearly signals that the FDA views eConsent systems as an inevitable next step in clinical research. For sites, shifting from a paper-based process to an electronic process will implicate written procedures, training requirements, regulatory compliance and relations with the IRB. As eConsent technologies evolve, sites should begin planning for the shift from today's paper-based consent process.

REFERENCES

1. Quorum Review Annual Site Survey (October 2015).

2. FDA Bioresearch Monitoring (BIMO) Metrics – FY'14, slide 3, accessed at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm (January, 2016).

3. Id. at slide 4.

4. FDA Bioresearch Monitoring (BIMO) Metrics – FY'07 to FY'14, supra n.ii.

5. Supra n.i.

6. U.S. Department of Health and Human Services, Food and Drug Administration Draft Guidance, Use of Electronic Informed Consent in Clinical Investigations Questions and Answers Guidance for Industry (March 2015).

7. Id. at p.5.

8. Id. at p.7.

9. 45 CFR 164.306.

10. 45 CFR 164.308.

11. Supra n. iv at p.5.

12. 21 CFR 50 Subpart B; 45 CFR 46.116 & 117.

13. See, e.g., ICH E6 Good Clinical Practice 3.1.2; Tri-Council Policy Statement (TCPS) 2, Ch. 6.

14. Supra n. iv at p.5.

15. Id.

16. Id.

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About Kinetiq

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