Quorum

eConsent: How to Improve Efficiency, Compliance, and Engagement

Kay Neth, Manager of Consent Form Development
Mitchell Parrish, JD, RAC, CIP, VP of Legal Affairs for Kinetiq

DESCRIPTION

Discover how the right eConsent tool will pay dividends by delivering real-world efficiency and improved compliance. Plus, get tips for choosing an eConsent vendor that will help you successfully transition away from paper.

TOPICS

• INTRODUCTION
• COMPLIANCE
• STUDY STARTUP
• PARTICIPANT ENGAGEMENT
• CONCLUSION

How to Improve Efficiency, Compliance, and Engagement with eConsent

Today, we are conducting 21st-century human subject research with 20th-century tools.

Paper plays a major role in today's research, and there are many reasons for continued reliance on paper-based processes in our industry, such as regulatory uncertainty, varying levels of technology integration at research sites, focus on competing priorities, and even resistance to—or fear of—change.

But because of the inefficient use of paper, we are seeing a shift in our industry. This, combined with the slow integration of technology into clinical research, the way technology changes our expectations and behavior, the emphasis on recruitment and site performance, and the opportunities offered by digital technology, eConsent is now at the center of this shift.

In December 2016, the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) published joint guidance related to the use of eConsent, which acknowledged, "The research community is showing increasing interest in using electronic media to supplement or replace paper-based informed consent processes."

Many sponsors have eConsent initiatives in play, whether developed independently or through industry work groups. As a large Institutional Review Board (IRB), Quorum Review can affirm that the use of eConsent is growing—and it has become increasingly clear that, with the right solution, eConsent can benefit research stakeholders, including sponsors,contract research organizations (CROs), research sites, and participants.

In the same way that digital technology changed how we interact with news media, books, and each other, eConsent will permanently change how researchers carry out consent discussions. Ultimately, those changes will give way to a revolution in what sponsors, CROs, IRBs, sites, and participants expect out of consenting.

With the movement gaining momentum and backing from regulatory agencies, industry stakeholders must now prepare for these changes by informing themselves about eConsent and its advantages, and determining what they want to gain from an eConsent tool.

This whitepaper offers practical guidance on how eConsent provides value, and what industry stakeholders should look for in an eConsent solution to ensure that value becomes reality.

The following pages contain a look at how eConsent affects research and how the right eConsent solution will enhance success in **three key areas**:

- Consenting compliance
- Study startup
- Participant recruitment and retention

This whitepaper also considers the **significance of selecting the right eConsent vendor, as well as what functionality to look for in an optimal eConsent solution.**

It is important to understand that when it comes to eConsent, you don't have to go big or go home.

Generally, discussion about eConsent emphasizes opportunities to include multimedia presentations, glossaries, and other user interface attributes. The excitement generated by the possibility of multimedia and interactive features represents the industry's desire to create better experiences for prospective participants during consenting.

But with the right vendor and the right functionality, eConsent can benefit the consenting process and research in the three key areas we outline in this whitepaper even if it is a simple, low-cost solution (for example, an application that converts a traditional paper consent form into an electronic format that research staff and participants can access on a laptop or other device).

Consenting Compliance

Today's research context is characterized by complexity—complex protocols, processes, and paperwork. That complexity, along with the pace of research today, is placing unprecedented demands on research staff, and human error can occur even among highly capable, well-trained research staff. Amid the logistical challenges of running a study, perhaps the signed copy of the paper consent form is lost instead of filed. Or perhaps a participant receives an outdated version of the consent form instead of the current copy.

Secondly, the complexity of consent forms can drive errors during consenting. A consent form might contain 10, 15, 20, or more densely written pages. Embedded on any of those pages might be a checkbox for consenting to an additional optional procedure; lines for initials, addresses, printed names, signatures, and signature dates—all awaiting completion by the participant (or the legally authorized representative, or LAR), the investigator, or another designee, and all at risk of being inadvertently missed during the consent process.

The rigor and pressure of research, combined with the complexity and page count of consent forms, creates a paper-based consenting obstacle course, laden with pitfalls. We ask research site staff to navigate that obstacle course every day, and to do so without a single misstep.

But missteps occur.

For example, from 2011 to 2016, the FDA reported 214 inspectional observations related to the mandate to obtain informed consent under 21 CFR 50.20, the failure to adequately document informed consent under 50.27 , and the failure to maintain documents evidencing informed consent under 812.140 (a)(3)(i).

To this day, errors related to informed consent continue to be one of the most common reasons for issuance of a Form 483 (inspectional observations) to investigators. For example, the FDA's published summary of its 2016 inspectional observations notes the top three as, as "failure to properly supervise the clinical investigation," "failure to maintain accurate case histories," and "failure to obtain informed consent in accordance with 21 CFR 50."

> Consenting errors undermine compliance, participant protection, participant engagement, and recruitment.

Paper-based consenting is a compliance risk and an operational inefficiency. Research sites are investing their staff hours (and, therefore, allocating budget) to prevent compliance lapses associated with paper-based consenting.

Right now, in the 21st century, research teams are maintaining paper files of multiple versions of multiple consent forms that are issued over the life of the study. They are maintaining original signed paper copies of consent forms. They are documenting who received a consent form and who signed it. They are documenting who has re-consented with a new version of a consent form. They are double- and triple-checking lengthy consent forms to verify that no signature line went unsigned, no date line went undated, and no checkbox went unchecked.

If despite the best efforts of their team members, a consenting error occurs, research sites must invest more staff hours in addressing the consequences. The resulting consequences range from documenting the issue in a deviation log to reporting the issue to the research ethics board to responding to an agency warning letter.

Consenting errors undermine compliance, participant protection, participant engagement, and recruitment. They can affect the reputation of an investigator or sponsor. They can also affect the integrity of research data. For example, if the FDA finds that a site has a pattern of consenting errors, it has the authority to prevent the sponsor from using that site's data in the marketing application.

Compliance failures—and the hours and budgets directed toward preventing and addressing compliance failures—don't have to be a part of 21st-century consenting. eConsent can help to eliminate the obstacle course and set the stage for error-free, efficient, and ethical consent documentation—if you have the right eConsent functionality and the right eConsent vendor.

Why not give sites a tool that prevents errors during consenting and enables site staff to spend less time on manual error prevention activities and more time on value-added activities?

FUNCTIONALITY THAT SUPPORTS COMPLIANCE

An eConsent solution should offer dashboard metrics with information pertaining to who has received a consent form, who has consented, and who requires re-consent. The dashboard should provide real-time, consolidated information, which decreases the possibility of failing to obtain informed consent, obtaining consent after a participant has undergone study procedures, or failing to re-consent participants in a timely manner (all mistakes that lead to FDA inspectional observations).

Version Control

An eConsent solution should have easy-to-use version control, which automatically pushes a new consent form (and any supplementary material) to the devices that research site staff and participants will use. This eliminates the risk that staff will accidentally consent participants with an outdated version of the consent form.

Document Storage

To mitigate the risk of failing to store the original signed consent form at the research site, a strong eConsent solution should have the capacity to store the e-signed documents. (Note that an e-signed document has the same validity as a wet, or hand-written, signature, assuming it meets compliance standards discussed later.)

Distribution and Tracking

Another consenting error is failing to provide a copy of the consent form to the participant or other signatory. (This refers to both the copy of the consent document for the participant to review on his or her own and the copy of the actual signed consent document after the consent discussion.)

An eConsent solution should easily allow research staff to email the template consent form and supplementary material used during consenting (such as a brochure about the study) to prospective and current participants; it should also track who receives a copy.

User Accounts

Ideally, the participant would have access to the signed consent form through his or her own eConsent account (similar to hospital systems allowing access to medical records). This functionality reduces the possibility of missing the requirement to provide participants with a signed copy of the consent form.

Document Controls

Other issues researchers encounter include consent documentation errors—for example, not obtaining the printed name, signature, or date of signature from a required signatory. When an entry is missed, well-intentioned staff might fill out a date or other information in the consent form on a signatory's behalf—but that "fix" itself is another consent error. To mitigate these risks efficiently, look for an eConsent solution with smart form logic that flags the consent process as incomplete if the study staff or participant has omitted a checkbox, initials, signature line, or date.

It is similarly important to know whether the eConsent tool automatically tracks the pages a participant has accessed and time spent on a given page. Typically the way to document whether a participant actually reads each consent form page is to have the participant initial each page and, of course, for the person conducting the consent discussion to gauge the participant's understanding of the study during the consent discussion.

> An eConsent solution should easily allow research staff to communicate with prospective participants before they enter the study.

While tracking the pages a participant accesses and for how long is not a gauge of participant comprehension of content, this tracking can feasibly replace participants initialing each page for documentation purposes. (Note also, however, that an eConsent solution should support this initialing process if a site or sponsor requires it: an eConsent solution's error-prevention functionality would eliminate the possibility of a page left "un-initialed" by a participant.)

FINDING A VENDOR

Beyond this specialized functionality, verify that the prospective eConsent solution is compliant with regulatory requirements for electronic signatures and security. With the right vendor, eConsent compliance doesn't have to be complicated. For example, for research in the United States, simply check for compliance with:

- The Food and Drug Administration Electronic Records and Electronic Signatures requirements under 21 CFR Part 11 (Part 11)
- The Health Insurance Portability and Accountability Act (HIPAA)
- The Health Information Technology for Economic and Clinical Health (HITECH) Act

As noted in the FDA's December 2016 guidance on eConsent, "IRBs, investigators, and sponsors may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements contained in 21 CFR Part 11."

In doing your due diligence in this area, make sure that your vendor can support its compliance claims: Ask your vendor about its third-party verification or external auditing for Part 11 and HIPAA/HITECH compliance.

In addition, to enable the same benefits in pediatric research, the tool should comply with the Children's Online Privacy Protection Act (COPPA). COPPA is enforced by the Federal Trade Commission (FTC) and imposes certain requirements on operators of websites and online services where there is knowledge that they are collecting personal information online from a child under the age of 13.

If the eConsent solution is online and is being used for a study recruiting participants under the age of 13, then COPPA may apply. Note that even collecting a name and assent signature is considered the "collection of personal information."

Finally, ensure your vendor is well-versed in standard consent form compliance elements, standard HIPAA compliance elements, and state-specific requirements for human subject research. These components can affect the content of the consent form—for example, state law can require placement of signature lines within the body of the consent form—and it is important to ensure your eConsent vendor's solution is flexible enough to accommodate those specialized requirements without issue.

Study Startup

With the right functionality, eConsent can positively shape study startup: it should be easy for participants to consent to the research, for sites to execute, and for sponsors and CROs to implement.

What does this mean, specifically? If the eConsent solution your organization is evaluating boasts the following functionalities, it is likely to have a positive impact on study startup.

IRB INTEGRATION

If your vendor lacks a relationship with an IRB or an understanding of IRB processes, your approval timeline will be extended, regardless of how basic or complex the eConsent solution.

IRBs require review of the consent form text, graphics, and user interface that participants might experience when they view and interact with the eConsent solution. IRBs also routinely review the processes and standards related to the use of eConsent, including the technology used, whether consenting is in-house or remote, whether an electronic signature (that complies with regulatory requirements for signatures) will be used in place of a wet/handwritten signature, and whether HIPAA-related and consent-related waivers are needed because of the lack of signatures.

Streamline the review process with an IRB-integrated vendor. What does IRB integration look like? It's simple: in an IRB-integrated eConsent ecosystem, the IRB has background in the eConsent solution and how it will be used, which reduces or eliminates questions or delays during the submission process and review. In addition, an IRB-integrated eConsent solution will be compatible with the IRB's logistics for issuing consent forms and approval documentation (and prevent administrative mistakes or lag time after review).

When choosing an eConsent vendor, ask whether your prospective vendor understands the IRB's review requirements. And ask whether its processes align with the IRB's processes for preparing consent forms for sites, especially on a multi-site study.

STUDY STARTUP DATA VISIBILITY

eConsent doesn't just shape and benefit the immediate consenting experience. The right tool should provide sponsors and CROs with real-time, recruitment-related information about users at the site level during study startup. Those insights help sponsors and CROs better understand the recruitment experience for sites, which ultimately paves the path to better understanding a site's startup experience.

To gain this type of advantage, ensure the prospective eConsent solution provides a sponsor or CRO with real-time information on:

- Target enrollment
- The number of prospective participants a site is in contact with
- The number of those participants who have been consented to the research
- When those participants consented

In addition, ensure the solution supports the site's recruitment efforts. An eConsent solution should facilitate distribution of consent forms and related materials to sites and prospective participants or their LARs before and after agreeing to participate in the research.

With that in mind, look for a cloud-based eConsent solution that can push the current, approved consent form to the devices from which it will be accessed at the site—this allows any site research staff member to go to a computer and be confident that he or she is viewing the most current version of each consent form, including translated consent forms.

From there, your eConsent solution should also enable the research site staff to easily route the consent form and related media used during the consenting process to prospective and current participants or their LARs, even before a study visit, with the understanding that unless remote consenting is occurring, participants will be consented at the study site.

An important corollary to this functionality: the eConsent tool should allow site

staff to lock the consent form, so that participants don't electronically sign it outside of the research site (in cases where remote consenting is not employed).

Participant Engagement

IMPROVING PARTICIPANT ENGAGEMENT AND RETENTION WITH ECONSENT

Benefits to study startup and recruitment gained from eConsent solutions do not exist in a vacuum. In fact, they are closely tied to the imperative that participants be informed about the research study before agreeing to participant. Unfortunately, low participant engagement and poor retention are common challenges for clinical trials.

Consider the 2013 Perceptions & Insights Study, *Report on Ineligible Participants and Those Who Terminate Participation Early*, prepared by Center for Information and Study on Clinical Research Participation (CISCRP). As described in the report, prospective participants who terminate their participation early noted higher levels of difficulty understanding the consent form and less satisfaction that their questions were answered during consenting, as compared with participants who completed their studies.

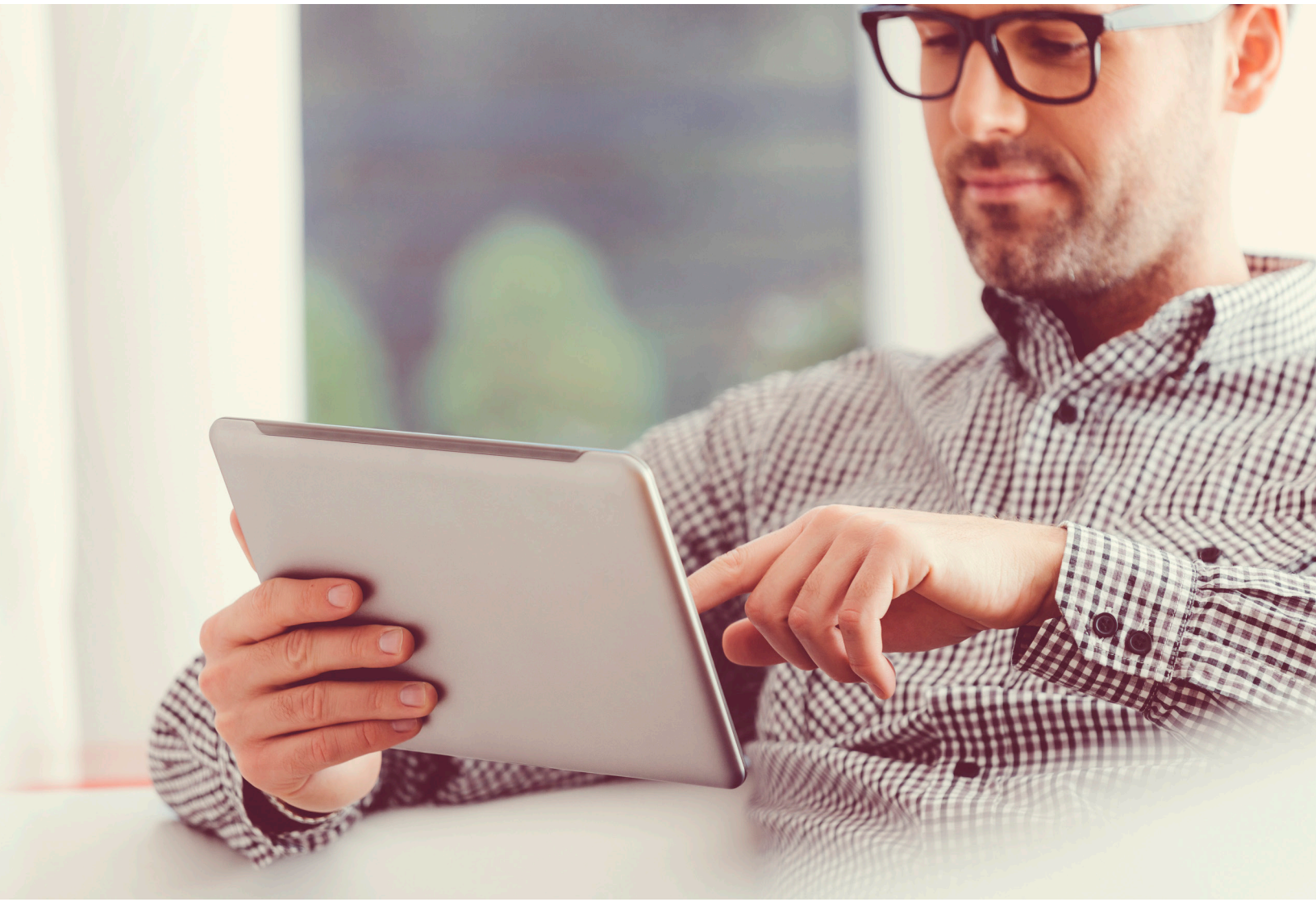
Specifically, the study found that:

- 35 percent of respondents who dropped out of research reported that it was "somewhat difficult" or "very difficult" to understand the consent form
- 89 percent of respondents who completed their study were "somewhat satisfied" or "very satisfied" that the consent form review addressed their questions; only 64 percent of drop-out respondents were "somewhat satisfied" or "very satisfied" in this area

This data emphasizes that participants who left studies said those studies did not align with their expectations, suggesting the consent process was not adequate in addressing those expectations.

It is not enough to simply provide understandable content and access to the principal investigator or research staff to answer questions. It is also necessary to deliver this content and messaging in a manner consistent with how people expect to receive and interact with information in today's world. Addressing the consent process holistically—from the content itself, to access to those who can answer questions, to modern delivery—will help address deficiencies enumerated in the CISCRP study and inform participants in a way that reduces their anxiety about participation while increasing their engagement.

In order to recruit and retain subjects, researchers should elevate the consenting process by engaging with those prospective participants in the manner they accustomed to—in today's world, and in the future, this typically means turning to the electronic medium to deliver consent.



HOW DOES ECONSENT ELEVATE THE CONSENT DISCUSSION?

Not only does the right solution improve the delivery of this critical information, but it also gives participants more ownership over the consent process. Ownership is a critical element of engagement in any system, and the right eConsent solution will invite participants to the table by giving them control in their own consenting process.

For example, participants can receive a digital copy of the eConsent, review it, and add questions that can be easily sent back to the research staff digitally. In this case, participants don't have to jot down questions on the consent form or send an email to study staff. This interaction means participants view materials on their own time with their own devices, and they can ask questions more easily.

The right eConsent solution should act as a vehicle for communication between research staff and the prospective participants and expand the reach of the site's recruitment and enrollment efforts. Such a vehicle is created, for example, by

providing participants an eConsent account through which they can access the consent form from whatever location and device they want.

Moreover, the right solution would ideally offer flexibility, allowing researchers to incorporate supplemental teaching tools—such as teach-back—into consent forms if warranted by the complexity of the trial. They could send these supplementary materials with the consent form, again to be accessed wherever participants choose. This flexibility serves to increase comprehension and, therefore, retention. Improved access to consent materials is key, but keep in mind that the eConsent solution must offer some means by which to prevent participants from signing those materials until it is appropriate to do so.

This all adds up to facilitating comprehension over the course of the study and helps ensure that consent is ongoing—it is easier for participants in a study to reference materials available through a cloud-based eConsent solution than it is to look through unwieldy paper documents. Plus, cloud-based access to the consent form and supplementary materials means participants can share this information with the people they want to talk to about their participation—their regular doctor, their families, or others.

By initiating the consent discussion earlier, eConsent increases the capacity for staff to have an in-depth discussion with participants about their specific concerns, as each party comes to the table more prepared. Participants are therefore more likely to feel that they know what to expect of the trial and that their concerns have been adequately addressed. This translates to a more positive research experience for them and an optimized and efficient trial for the researchers.

Today the consent process often resembles a rote presentation, and research suggests that participants do not read consent forms or experience the intended effect of the process. eConsent moves us in a better direction—toward true informed consent, offering participants ownership in their participation. This is good news for recruitment and retention.

Conclusion

Research stakeholders evaluating eConsent solutions should expect the following benefits, at a minimum, brought to life by the key functionalities and flexibility discussed in this whitepaper.

First, stakeholders should expect improved consent documentation compliance. The solution should have an easy and transparent metrics dashboard with readily accessible logs for all participants in at all stages of the consent process. It should also store e-signed documents, and research staff should be able to easily send the consenting materials to participants through the platform. Most importantly, the solution should have tight controls on documentation, including ones that ensure all required initials, checkboxes, dates, and signature fields are complete.

Stakeholders should also expect the eConsent solution's compliance with applicable regulations. This includes Part 11, HIPAA, HITECH, COPPA, and potential state-specific requirements. The FDA eConsent guidance states you can rely on a statement of compliance from the vendor, but this does not absolve an organization from liability. Make sure to press the vendor on compliance documentation.

Next, the solution should create efficiencies in study startup three ways.

1. Integration with an IRB's existing review process, shortening review of the eConsent portion to days instead of weeks.
2. Real-time enrollment metrics, allowing the sponsor to verify study-wide enrollment easily and quickly.
3. Distribution of study materials to would-be participants before the first site visit, supporting site-level recruitment efforts.

If chosen carefully, the right eConsent solution will optimize research for sponsors and CROs.

Lastly, the right eConsent solution will enhance participant engagement and retention by engaging prospective participants early and often. Doing so will offer ownership in the consent process, allowing participants more control over what information they receive and how they deliberate on their decision to join the study. A more engaged participant base will lead to better retention and overall study integrity.

The way the world communicates is evolving, and today, even participants in clinical trials and behavioral research expect information about the study to be conveyed in a manner that is consistent with how they receive all of their information: electronically. The research community will ultimately benefit from an electronic makeover with eConsent, improving the consenting process for researchers and participants alike.

There are many criteria by which researchers will evaluate eConsent solutions, and each organization has its own requirements—be they related to compliance, budget, or ease of use. But the right solution will meet all of these requirements and more; and ultimately, the solution that does so is the solution that makes adopting eConsent easy for research stakeholders at all levels.

If chosen carefully, the right eConsent solution will optimize research for sponsors and CROs. And, most importantly, it will give confidence to everyone involved in research—from participants to the IRB to researchers—that the consent discussion is complete and ongoing, and that participants are truly informed.

About Quorum

In 1991, the founders of Quorum saw a need for an IRB that protected human subjects while providing high-touch customer service. That's exactly what Quorum delivers. Each member of our team brings a wealth of experience in clinical research human subject protection—plus the knowledge, reliability, accuracy, and speed that matters when getting products to market. Our comprehensive customer solutions are tailored to meet the demanding needs of our customers.

OUR MISSION:

To protect study participants through the highest quality reviews, build a community dedicated to the well-being of all people, and drive research forward together.

QUORUM SUPPORTS ITS MISSION BY FOCUSING ON OUR CORE VALUES:

- Service
- Teamwork
- Respect
- Integrity
- Visionary
- Excellence

Quorum Review IRB is the first name in streamlined, service-centered independent ethics and regulatory review. The Quorum difference is One-Touch Collaboration™. Your research benefits from an outstanding service experience, a single point of contact, one study startup timeline, and a true single board review—which is why Quorum is the preferred central IRB. Beyond traditional institutional review board services, Quorum offerings include single IRB (sIRB) services for institutions and the world's first IRB-integrated electronic informed consent solution: Q Consent™. Kinetiq, the consulting and technology division of Quorum, provides services that enhance and optimize the clinical research process.

Quorum has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2006. AAHRPP's "Full Accreditation" emblem signifies that Quorum Review consistently demonstrates excellence in comprehensive protections for research subjects while facilitating the highest quality research processes.

To learn more about eConsent, visit
www.QConsent.com

1501 Fourth Avenue, Suite 800, Seattle, WA 98101 | www.QuorumReview.com
206 448 4082 or 877 472 9883 | email: info@QuorumReview.com

1501 Fourth Avenue
Suite 800
Seattle, WA 98101

D/206 832 0808
T/ 866 810 1128
F/ 206 448 4193

QuorumReview.com
QConsent.com

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