Healthcare

ALERTBULLETIN®

A Risk Management Update | 2026 Issue 3

Digital Informed Consent: Balancing Innovation and Compliance

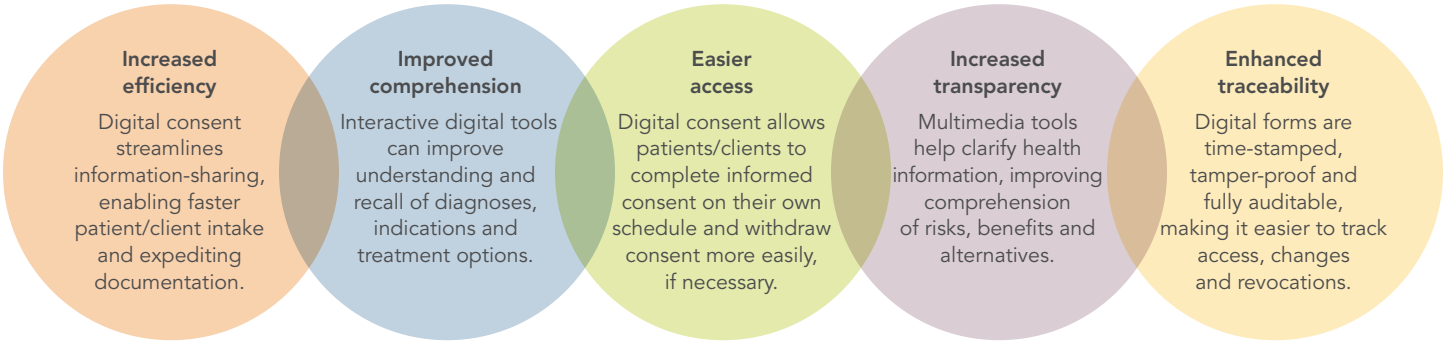
Digital informed consent is a comprehensive, technology-enabled process that educates patients/clients about the proposed course of care, obtains their authorization and electronically documents their consent. (In contrast, *electronic* or *e-consent* refers more narrowly to capturing patient/client consent and signature by electronic means rather than on paper – for example, completing a PDF form on a tablet during an office visit.) As technology evolves, providers increasingly deliver consent-related information through a combination of digital tools, remote platforms and multimedia formats in lieu of hard-copy materials.

These advancements in the consent process have produced a broad range of benefits, including greater convenience and efficiency, as illustrated below. At the same time, however, the shift to digital consent introduces a range of potential legal, clinical and operational liabilities, including communication gaps between provider and patient/client, digital access inequities, electronic health record documentation challenges and regulatory compliance concerns. To counter these risks, providers and organizations must implement digital informed consent systems in a thoughtful manner and closely monitor results.

This edition of *AlertBulletin*® offers guidance for healthcare leaders and providers seeking to maximize the benefits of digital consent while minimizing associated exposures. The bulletin provides an overview of commonly used tools and basic clinical applications. It also addresses common challenges in digital informed consent and provides strategies to help ensure patients/clients comprehend the nature, benefits and risks of the proposed treatment, as well as alternatives. Finally, a sidebar on page 3 highlights key legal and regulatory requirements to consider when obtaining electronic signatures (e-signatures).

Key Advantages of Digital Informed Consent

At present, research on the effectiveness of digital consent remains limited, but preliminary findings suggest it may offer the following benefits, among others:



See Goldschmitt, M. et al. "Digitalizing Informed Consent in Healthcare: A Scoping Review." *BMC Health Services Research*, volume 25: article No. 893, July 2, 2025.

Basic Tools

Whether traditional or virtual, informed consent must remain collaborative and individualized, with digital tools used to reinforce, not replace, the required provider-patient/client discussion. The following modalities, among others, are used to augment one-on-one consent discussions:

- **Telehealth platforms** that facilitate end-to-end remote consent processes.
- **Website tutorials** that provide self-paced education on risks, benefits and procedural expectations, among other issues, prior to a face-to-face provider discussion.
- **Video supplements** that complement verbal explanations by the provider.
- **Digital questionnaires** that capture preoperative data and inform the consent process.
- **Interactive web applications** that offer personalized walk-throughs of procedures and treatments, including provider guidance and important reminders.
- **Artificial intelligence-driven platforms** that facilitate interactive Q&A functions and automatically generate documentation.
- **Virtual reality (VR) or augmented reality (AR) devices** that provide immersive, interactive experiences, enabling the patient/client to better anticipate and understand treatments – e.g., patients/clients may use a VR headset to preview a planned procedure, or use AR features on a tablet to view three-dimensional anatomy overlaid on diagnostic images.

Clinical Applications

Tool selection should be guided by the procedure/treatment and the patient's/client's specific needs. When used appropriately, digital tools may enhance informed consent in the following situations, among others:

- **Visual explanations of routine procedures,** such as IV therapy, blood transfusion, bedside treatment, radiological procedures and standard surgeries.
- **Preoperative or procedural education,** delivered through self-paced audiovisual modules, on such topics as surgical care, oncology treatment and reproductive health.
- **Research studies that require tailored consent approaches,** including small or specialized studies and decentralized trials that allow participants to provide consent remotely. (See Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors, from the U.S. Food and Drug Administration, August 2023.)
- **Pediatric care,** with materials designed to effectively inform children, as well as parents or guardians.
- **Remote care environments,** where a conventional in-person discussion is impractical.

Challenges and Preventive Measures

Healthcare organizations, practices and solo providers that utilize digital consent should be aware of the following areas of potential liability and take appropriate measures, as suggested below, to counter these risks:

Inappropriate patient/client selection. Digital informed consent is not appropriate for everyone. Cognitive, language, visual, and technological or access barriers can limit a person's ability to understand and engage with online materials.

- **Ask patients/clients if they are willing or able to give their consent digitally,** or would prefer the conventional hard-copy approach.
- **Set clear criteria for when digital consent is appropriate,** including screening for cognitive, sensory, motor and digital-literacy barriers to meaningful participation.
- **Be prepared to utilize paper-based consent when needed,** ensuring that legal and documentation requirements are met.

Over-standardization. While use of standard forms may help prevent omissions, excessively rigid templates could potentially impede explanation of specific diagnoses or treatment plans.

- **Include free-text fields in templates** to accommodate additional notes on risks, alternatives and other pertinent clinical content.
- **Remind providers that informed consent is primarily a patient/client education and communication process,** not an administrative task.
- **Regularly review consent templates** to ensure ongoing regulatory compliance and clinical relevance.

Lack of patient/client understanding. Health literacy varies widely, a fact that should be kept in mind when drafting and reviewing consent materials.

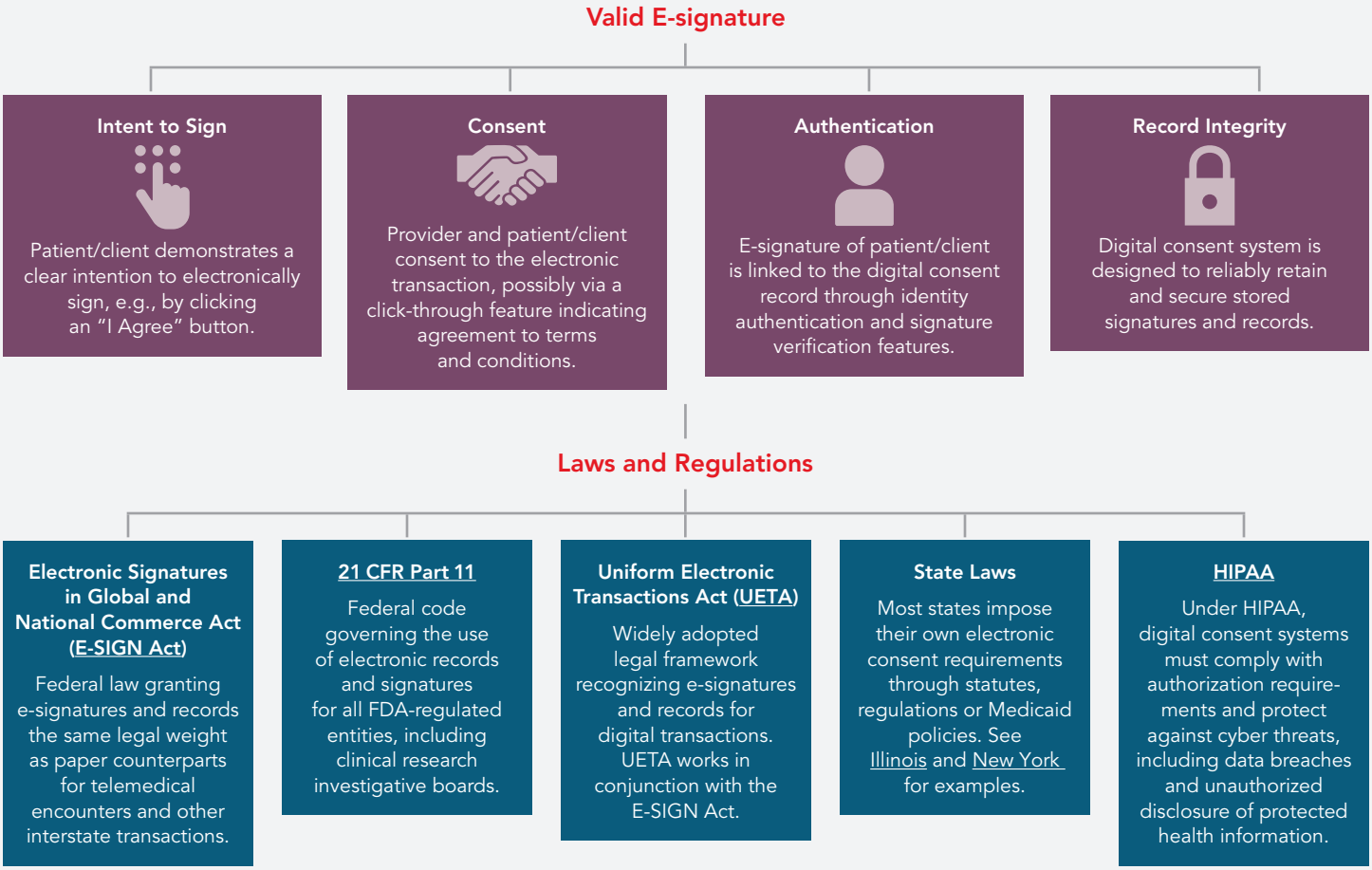
- **Use plain language in consent materials** and ensure they are written at a reading and knowledge level geared to the average patient/client.
- **Incorporate audiovisual educational tools** to reinforce important concepts and support different learning styles.
- **Integrate comprehension checks** – such as brief multiple-choice questions – into the digital process to confirm patients'/clients' understanding of the treatment's nature, benefits and risks.
- **Instruct providers to confirm patients'/clients' comprehension** of consent-related information and to document their verification in the healthcare information record.
- **Ensure that patients/clients know how to access and use the website portal,** if their consent will be obtained through it.

Insufficient documentation. While digital consent forms and other materials can help convey essential information, providers remain responsible for documenting that patients/clients understood the material, had the opportunity to ask questions, received appropriate responses, and participated in an open and mutual discussion. Failure to do so may have liability consequences.

- **Clearly state in written policy that digital consent does not replace face-to-face discussion** and serves only to support critical dialogue and documentation.
- **Include a provider attestation in digital forms,** whereby providers confirm the discussion occurred and patients/clients understand the significance of what they are signing.
- **Require a separate provider note in the healthcare information record of the key risks reviewed,** as well as questions asked, alternatives discussed and clarifications provided.
- **Note if VR, AR or other digital tools were utilized** to enhance the patient/client educational aspect of the informed consent process.
- **Maintain an auditable record of digital consent and supporting clinical documentation,** and perform periodic quality audits.

Legal and Regulatory Requirements

For digital informed consent processes to be valid, they should be functionally equivalent to traditional paper-based methods, providing the same level of notice, comprehension and affirmative agreement. The diagram below illustrates four pillars of a legally binding e-signature and identifies some key laws and regulations necessary to achieve compliance:



Inadequate accessibility and equity safeguards. Digital consent policies should take accessibility and equity issues into consideration, as failure to do so may result in unequal patient/client access to care or invalid consent.

- **Check for connectivity across device types** – e.g., mobile phone, tablet, desktop – as well as operating platforms and browsers.
- **Ensure that providers offer interpreter support** and translated written materials, when needed.
- **When necessary, offer assistive devices,** such as screen readers and magnification tools.
- **Measure patient/client access to and comprehension of the digital informed consent process** as part of performance improvement initiatives, implementing corrective actions as needed.

Privacy and security lapses. As e-consent processes are potentially vulnerable to unauthorized access, data breaches and potential system disruptions, they require effective, up-to-date security safeguards.

- **Check that digital consent systems are in compliance** with applicable privacy, security and data protection requirements.
- **Limit access to consent records to authorized personnel,** based on their job responsibilities.
- **Ensure that digital consent systems produce clear audit trails** that document access, e-signatures, modifications to consent forms and patient/client revocation.
- **Develop contingency plans for system outages or cyber incidents,** including procedures for conventional paper-based consent when necessary.

Like many other healthcare-related processes, informed consent is being transformed by digital technology. Interactive platforms and multimedia tools make vital information available to patients/clients more quickly and compellingly. However, an over-reliance on technology can also make the informed consent process – which is fundamentally a discussion between provider and patient/client – more one-sided and impersonal. The suggestions included in this publication can help ensure that digital consent policies and procedures help strengthen communication, compliance and documentation, while minimizing liability exposure.

Quick Links to CNA Resources

- *AlertBulletin*® 2026-Issue 1, "Electronic Healthcare Records: As Systems Evolve, New Risks Emerge."
- *inBrief*® 2025-Issue 1, "Patient/Client Portals: Maximizing Benefits, Minimizing Risks."
- *Vantage Point*® 2024-Issue 2, "Telemedicine Update: Coordinating Remote and In-person Care."

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