Your Consent Process Can Make or Break Your Studies

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Inside This Whitepaper

Disruptions due to COVID-19 paired with a slew of new guidance from regulatory bodies has catapulted the clinical trial industry into a period of digital transformation.[1] More sponsors and CROs are beginning to adopt decentralized solutions and embrace digital workflows, yet informed consent continues to rely heavily on paper-based processes. **Lots and lots of paper.**

If you're wondering how much paper, consider a recent study that found that the average 1,500-bed hospital prints over eight million pages per month at the cost of four cents per page.[2] Not including printing equipment, that adds up to nearly $3.8 million each year.

And while a majority of healthcare organizations are digitizing their processes with eClinical solutions, 76% still admit to printing their consent forms.[2]

Consent is a critical part of the patient journey. Ensuring patients are fully informed and willing to participate in a trial is an ongoing process. Study and site managers must confirm that patients receive all of the necessary information to make a free and informed choice before consenting to participate in a study - and continuously throughout the trial. Only then can clinicians fulfill the legal and ethical responsibility of their trials while bringing their medical breakthroughs to market.

We will explore the role consent plays in the success of your trials and how the industry is shifting towards greater adoption of eConsent to strengthen patient comprehension, adherence, and retention.

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What is Informed Consent?

In its simplest form, informed consent refers to the explicit permission granted by a patient after fully comprehending all possible risks and benefits of their involvement in clinical research.

Consent cannot be considered informed unless the consenting individual understands:

- All possible health risks involved in their participation
- Any potential benefits as a result of their involvement
- Comprehension of all procedures required of them
- Time, travel, monetary, and personal commitments required during the course of the study
- The extent to which their personal health information (PHI) will be collected and maintained
- The voluntary nature of their participation and that they may discontinue participation at any time

The goal of informed consent is for the patient to be educated and engaged in their healthcare decision and fulfill the legal and ethical responsibility of the trial. Although most healthcare professionals understand the importance of achieving informed consent, it continues to plague trials across every therapeutic area.

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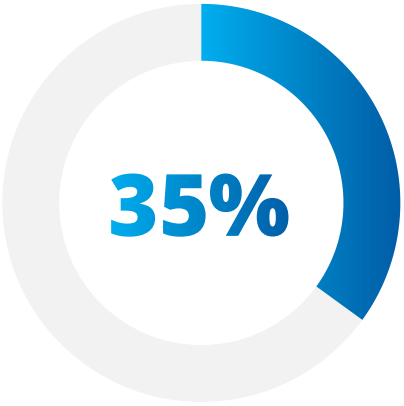
Why Informed Consent Matters and What Clinicians Need

In order for informed consent to take place, the patient must receive all of the information they need to make an educated decision on their involvement with the study. For the process to work effectively, the information provided to patients must be complete, relevant, and—most importantly—easy to comprehend.



Patient Drop-Outs Found Consent Form Confusing

In traditional research, the informed consent form (ICF) and patient collection forms are excessively long and littered with medical jargon that is hard to digest. As a result, nearly 30% of patients are unaware of basic aspects of their involvement, such as randomization assignment, the possibility that they could receive a placebo, or the fact that an adverse effect (AE) could occur.[3] Even worse, 35% of patients who dropped out of trials cited the consent form as confusing.[4]

If an informed consent form fails to educate a patient on critical components, it is not serving its most basic function. Clinicians need to get back to the heart of consent, instead of viewing it as an administrative requirement. In order to do this, it helps to look at some of the common mistakes that prevent consent from being truly informed:

Challenges in Achieving Informed Consent:

Limited Health Literacy—One-third of American adults are estimated to suffer from below-average health literacy, making it difficult for them to make informed decisions about their health.[5]

Consent Built for Clinicians—Clinicians often prioritize consent workflows that satisfy regulatory requirements over writing guidelines tied to patient behavior.

Confusing Medical Jargon—Patients struggle to understand medical terminology, affecting their ability to adhere to the treatment. Without plain English study guidelines, patients may be lacking comprehension and are therefore not compliant.

Paper is Prone to Human Error—Workflows beholden to paper processes are subject to human-error as paper gets misplaced or incorrectly entered into the system.

Lack of Consent Workflows—Consent needs to be given at several stages throughout a trial. Many clinical teams overlook consent workflows and lack the ability to detect patient comprehension throughout the course of a trial.

Not Built for Speed—Younger generations are more likely to skim or only read certain parts of a consent form in detail and 77% of patients report signing the form within 24 hours of receiving it.[4]

Keeping all of this in mind, it is critical that Clinical Opertations teams build processes to establish consent early in the trial and maintain it throughout the course of the study:

What Clinicians Need from Consent Forms	What Patients Need from Consent Forms
◉ Provide patients clear and effective information so that they are truly informed when making a decision to participate. ◉ Effectively obtain the legal informed consent of the patient or the patient's legally authorized representative. ◉ Reduce inspection findings and establish submission considerations for health authorities, IRBs, and ethics committees. ◉ Streamlined site workflows to reduce complex and time-consuming explanations, paperwork, and quality risks due to human-error. ◉ Benchmark workflows to identify if comprehension was effectively achieved. ◉ Process efficiencies for re-consenting, remote monitoring, and reducing errors.	◉ Information in an understandable language and format. ◉ Access to information that a reasonable person would require to make an informed decision about their health. ◉ An opportunity to discuss the information with a healthcare professional while minimizing the possibility of coercion or undue influence. ◉ Avoidance of exculpatory language that appears to waive the patient's legal rights or releases the trial agents from liability or negligence.

Why Informed Consent is Increasingly More Complex

Participants have to give consent before screening takes place in a study. At the same time, clinicians have to confirm that the patient understands the requirements, as well as the science complexity, to ensure patients are truly adhering and comprehending. But evaluating a patient's comprehension can be difficult.

Clinicians have both a legal and ethical responsibility to discuss the risks and benefits of clinical research with their patients. Yet, on average, healthcare professionals spend as little as six minutes training patients on the use of medication.[6] Confusion around processes, protocols, and expectations continues to be a leading reason why patients drop out of trials and failure to obtain consent is one of the top ten reasons why medical malpractice claims are filed.[7]

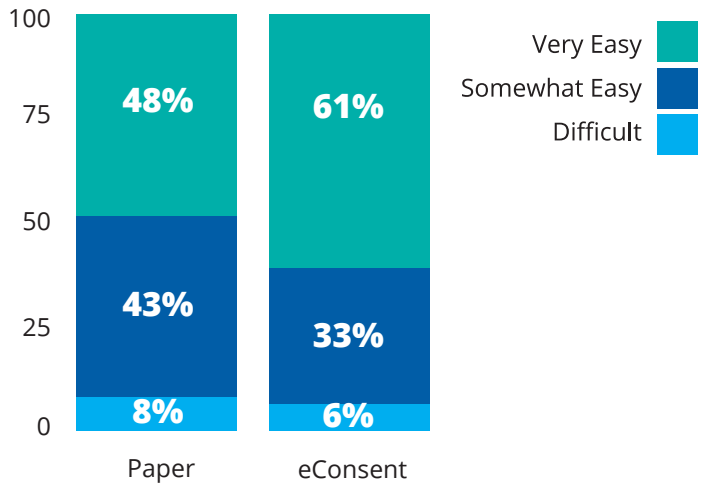
Average Time Spent Training Patients

Studies continue to find that when clinical research depends on a combination of paper consent forms and unstructured conversations with healthcare workers, few participants walk away feeling informed or being able to recall and comprehend what was shared with them. And each time a patient withdraws from a trial due to non-compliance, it costs a sponsor 3 times as much to recruit a new patient.[8]

To compensate, clinicians often attempt to standardize participant consent forms. This usually results in lengthier documents that are more geared towards satisfying regulatory requirements rather than prioritizing patient information and behavioral questions. Unsurprisingly, there is evidence that as consent forms grow longer, they become harder to comprehend and result in higher patient drop-out rates.[9] Additionally, as consent forms get longer and more confusing, they directly result in lost time and revenue for sponsors, lowered adherence rates for patients, and they jeopardize trust in the clinician-patient relationship.

Considering that 85% of clinical trials fail to recruit enough patients and 80% are delayed due to retention problems and high drop-out rates, researchers need every advantage to strengthen patient comprehension.[10] Streamlining consent forms electronically - also known as eConsent - can not only help improve enrollment and retention issues, it can help establish better trial continuity due to higher comprehension and lower drop-out rates.

A 2019 study examining patient perceptions aimed to look at how eConsent impacted overall patient comprehension.[4] A majority of eConsent patients (94 percent) found the forms to be easily digestible. This was especially true for patients 34 years or under, who traditionally have a lower health literacy than older generations.



How eConsent Unlocks the Door to Patient-Centricity

eConsent is more than a conversion of paper consent forms to an electronic version. eConsent can be the bridge that improves participant engagement in clinical trials through a variety of patient-centric workflows.

eConsent is helping clinicians achieve the following outcomes:

- **Flexibility—**Support in-clinic or remote consent workflows and expedite re-consenting workflows with eConsent solutions that support paper, electronic, and bring-your-own-device (BYOD) options
- **Scalability—**Standardized workflows help increase consistency across teams and sites so your processes can scale with your needs.
- **Unified Systems—**Centralize your consent information and increase transparency with a unified dashboard.
- **Real-Time Reporting—**Accelerate oversight with real-time access to consent progress data.
- **Compliance—**Protect patient's PHI with encryption and workflow-specific permissions that meet or exceed global compliance regulations.
- **Comprehension—**Enrich content with digital features, gamification, and quizzes to encourage patients to engage and interact with content without sacrificing global compliance.

IRBs & eConsent

Another key aspect of the consent process is the role of Institutional Review Boards (IRB). These independent entities are comprised of medical professionals and advocates who protect patient rights in clinical research. For years, the industry avoided eConsent due to resistance from IRBs and regulatory bodies. As many trials suffered disruptions due to COVID-19 and increased pressure was placed on creating patient-centric workflows, IRBs have begun to embrace electronic and remote consent options to protect patient safety.

Similarly, the U.S. Food and Drug Administration (FDA) and U.S. Office for Human Research Protections (OHRP) have publicly supported eConsent in clinical research since 2016. A guidance document issued states that, "electronic processes to obtain informed consent may use an interactive interface, which may facilitate the subject's ability to retain and comprehend the information."[11]

As governing bodies and IRBs embrace eConsent in a larger way, clinicians should keep pace with their progress. A high-quality eConsent should be able to support IRB-approved workflows and even upload IRB-approved paper consent documents to avoid re-approval requirements for multimedia consent experiences.

Building Consent Into Your Patient Journey

eConsent solutions are helping clinical teams build consent workflows organically into their patient journey. Here are ways that teams can approach building consent into their patient journey from the ground up:

- Use initial onboarding as a time to clearly, concisely, and directly explain the patient's expectations, answer any specific questions they have, and introduce them to new processes or decentralized technologies.
- Offer extended discussions with patients to address fears and anxieties they're facing before providing informed consent documentation.
- Throughout the trial, build processes to check in with patients at regular intervals and offer a space for questions, explicitly enquire about any issues, and make them aware of additional support.
- Don't make consent difficult for non-medical personnel to digest. Use plain language and avoid heavy medical jargon so patients can understand what is being asked of them.
- Offer translation in local languages (and ensure the translated information is still easily digestible).
- Don't assume lack of questions means patients understand the consent forms. Actively check on their comprehension throughout the consent process.
- Enrich eConsent forms with engaging media such as video and audio that are more friendly ways of communicating with a lower health literacy population.
- Consider advanced digital features like quizzes or gamification that participants can use to learn about the trial without sacrificing compliance.
- Provide supplemental information to the consent form that patients can review for additional information. This could be in the form of educational videos or informational pamphlets.

As simple as it might sound to translate your medical guidelines into "plain English", many researchers still struggle. Experts suggest writing guidelines using high behavioral specificity in conjunction with "plain English" study guidelines. This simple, yet effective method has been shown to result in stronger patient adherence, more positive attitudes in patients, and better perceived control over following the guidelines.

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The Future of Informed Consent Begins with You

Informed consent shouldn't come at the expense of your go-to-market strategy. With the use of a flexible, integrated eSuite that is designed to support both in-clinic and remote consent workflows, you can afford your patients better comprehension and comfort with trial participation and your clinical teams with more peace of mind.

Increased access and visibility into live consent metrics will help improve oversight so you can make strategic decisions, while improving data transparency across broad study teams. Enhance your consent workflows further by embedding them with media-rich videos, audio, and gamification options that allow patients to better understand trial requirements. And accomplish all of this on an encrypted service aimed to accelerate your oversight without sacrificing global compliance regulations.

Digital transformation has radically changed how clinical trials operate in a post-COVID world. Bring your consent process into the digital age and see the benefits it can have on your patients, your sites, and your trials as a whole.

About the Author

Melissa Newara is an experienced clinical trial technology professional with over 16 years in the clinical research space. Serving as Medrio's eSource Subject Matter Expert, she supports customers in understanding industry trends and regulations and helps to identify ways to optimize data collection by focusing on the patient and site experience.

Melissa's deep-rooted understanding of patient engagement and eSource collection stems from her extensive background working within clinical research in neuro-oncology, multiple sclerosis, behavioral health and gastroenterology. Most recently, she focused her work in eCOA as a clinical solutions specialist and a proposal operations manager. Melissa received her Master's in Psychology from Drexel University in 2007.

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