

News and Perspectives

Informed Consent in the AI Age: Why and How Documentation Must Change

Hankun Su, JMIR Correspondent

Abstract

To conduct an AI-related clinical trial, researchers must first make sure that participants consent to and fully understand what they're agreeing to. But what if the researchers themselves don't fully understand? In this *News and Perspectives* article, JMIR Correspondent Hankun Su reports on the unique challenges involved in AI-related clinical trials and how informed consent practices must evolve.

Key Takeaways:

- Traditional informed consent models are structurally misaligned with AI-driven clinical trials, where providers often lack the technical expertise to explain algorithmic risks and data governance.
- Rather than relying on providers to give verbal explanations, consent forms in AI trials must evolve from supporting documents into educational resources that can stand alone.
- Structured frameworks, like the Minimum Requirements for Informed Consent in AI-Related Clinical Trials (MRIC-AI), offer a practical pathway to bridge this gap.

Hankun Su is an MD/PhD candidate specializing in translational medical innovation and ethics. In this op-ed, he reflects on how AI is changing what is required for informed consent and describes the [new informed consent framework](#) he and his colleagues have developed for AI-related clinical trials.

[Informed consent](#) is the ethical and legal cornerstone of clinical research, designed to protect participant autonomy through transparent disclosure of risks, benefits, and procedural details. This critical dialogue is, however, still largely anchored in a paradigm developed for conventional pharmaceutical interventions, creating, as clinical research enters the era of [AI](#), a gap between the nature of AI-driven research and the mechanisms intended to protect participants.

While conventional consent frameworks assume static interventions and predictable outcomes, AI introduces adaptive algorithms and data dependencies. For example, [an AI system](#) may continuously update its treatment recommendations based on real-time patient data rather than administer a fixed drug dose, changing the risks a participant might be exposed to over the course of a trial.

Current documents fail to adequately capture these complexities. In our [recent study](#) for example, we found that 55% of AI-related clinical trial consent documents fail to disclose the type or role of AI, 18.4% omit critical risks, and only 14% meet basic readability standards.

Addressing the scale of this disconnect requires moving beyond incremental adjustments to re-examine the foundational assumptions of consent in the context of adaptive, data-intensive technologies.

The Clinical Communication Gap

Consent documents must now carry greater informational weight and importance because of how AI has disrupted the traditional clinician-patient information exchange.

[In conventional clinical research](#), investigators and treating physicians typically have enough understanding of the intervention to answer participant questions, clarify ambiguities in consent materials, and contextualize individual patient risks. The consent document functions as one component of an interactive educational process; its inadequacies can be remedied through dialogue.

[AI-related trials disrupt this compensatory mechanism](#). Many clinicians lack the specialized training and time required to fully understand and keep up with AI as it evolves. When participants ask whether an AI system performs equally well across demographic groups, how their data will be used to refine future model versions, or what “algorithmic analysis” means for their specific care pathway, [clinicians may lack](#) the technical vocabulary, institutional access, or confidence to respond accurately. This is not a failure of individual competence; it's a structural mismatch between current clinical training and the demands of AI-integrated research.

In this context, the consent document transitions from a validation reference to an essential, stand-alone resource. Participants must be able to extract comprehensive and comprehensible information directly from the text without relying on clinician mediation. Documents that use vague terminology, omit material details, or exceed accessible

reading levels create an informational failure that undermines genuinely informed consent.

Consequences of Informational Failure

When consent documents fail to serve as adequate, stand-alone resources in the context of clinician communication gaps, there are three broad consequences.

[Patient safety](#) is compromised because participants cannot independently identify or escalate concerns. If a document does not clearly explain performance limitations, bias risks, or data reuse pathways in accessible language, and clinicians cannot supplement this information verbally, participants may not recognize when something may be wrong. Safety monitoring becomes dependent entirely on investigator vigilance and automated systems, removing the protective layer that informed participants traditionally provide.

Public trust is eroded when participants find that neither their clinicians nor the provided materials can offer transparent answers. This distrust has been intensified by high-profile ethical failures, such as the case of [Mei](#), a 6-year-old who died following experimental gene-editing therapy. Her parents received informed consent materials that failed to adequately disclose risks or clarify significant financial conflicts of interest, casting serious doubt on the informed consent process. Although that tragedy occurred outside the AI domain, it has become a reference point in broader public discussions of clinical research transparency. Cases like this can intensify skepticism among the general public, leading vague disclosures to be interpreted as deliberate concealment rather than accidental omission. This could reduce patients' willingness to participate in research, threatening the viability of novel research, including AI-related trials.

Finally, enforcement mechanisms remain structurally misaligned with this shifted burden. Institutional review boards continue to evaluate consent documents against criteria designed for contexts where clinician dialogue compensates for textual limitations, and without standards assessing whether these documents can function adequately as stand-alone resources.

Consent Forms as Stand-Alone Educational Resources

Addressing these challenges requires fully redesigning consent documents, including crafting risk disclosures calibrated to varying health literacy levels and incorporating visual representations of data flows and model behavior, plain-language explanations of technical concepts, explicit acknowledgment of clinician knowledge boundaries, and structured guidance for participants seeking additional information. Documents must anticipate questions clinicians cannot answer and provide accessible responses within the text itself.

“The adequacy of informed consent in AI-related clinical trials ultimately depends on whether documents reflect the actual conditions under which participants make decisions. When clinicians cannot serve as reliable interpreters of AI systems, consent materials must carry the burden of enabling genuine understanding.”

Our team's [Minimum Requirements for Informed Consent in AI-Related Clinical Trials \(MRIC-AI\)](#) framework offers a possible solution. The model moves beyond static disclosures by establishing tiered standards that scale with algorithmic complexity and risk. The MRIC-AI framework mandates not only transparency regarding AI roles and data governance but also enhanced disclosures (eg, around the potential for bias or risk of patient data being identified) for high-stakes applications. By integrating strict readability limits, visual aids, and dynamic consent mechanisms (eg, committing to provide patients with updated information as AI systems evolve), the framework ensures that informed consent evolves from a bureaucratic hurdle into a robust, ongoing dialogue capable of safeguarding patients' autonomy in the age of AI.

The MRIC-AI framework is not without limitations. It requires validation across diverse contexts, its implementation demands resources some sites may lack, and its effectiveness depends on whether and how different participants engage with written materials.

Complementary approaches should be explored in parallel. These include, for example, using digital “just-in-time” consent interfaces to give relevant explanations in stages, when they're needed, rather than providing comprehensive information up front; embedding independent patient educators within trial teams to supplement both clinicians and documents; and using participatory design processes to ensure materials address actual participant questions rather than assuming participants' information needs.

The Future of Informed Consent in the AI Age

The adequacy of informed consent in AI-related clinical trials ultimately depends on whether documents reflect the actual conditions under which participants make decisions. When clinicians cannot serve as reliable interpreters of AI systems, consent materials must carry the burden of enabling

genuine understanding. A fundamental realignment of ethical infrastructure with contemporary research realities is needed.

For institutional review boards, adopting frameworks like the MRIC-AI as review benchmarks, establishing reviewer training on AI-specific stand-alone document adequacy, and requiring usability testing with representative participants would improve oversight. For investigators, designing consent materials that anticipate clinician knowledge gaps, conducting pretrial assessments of participant questions that clinicians cannot answer, budgeting for independent educational support, and creating feedback mechanisms for document improvement would advance participant-centered

practice. For policymakers, developing standards for stand-alone consent document adequacy in AI trials and supporting open-source tool development would enable broader adoption.

Frameworks like the MRIC-AI offer actionable starting points, but the deeper imperative is recognizing that participant autonomy in AI trials depends on information ecosystems designed for the world as it actually functions, not the world as we wish it were. The legitimacy of AI-driven clinical research rests on building consent practices that are honest and transparent about current limitations while rigorously addressing them.

Keywords: artificial intelligence; informed consent; clinical trials; research ethics

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Su H

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