

What Are the Consent Requirements for AI Healthcare Applications?

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Abstract

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The New Frontier of Patient Consent in the Age of AI

The integration of Artificial Intelligence (AI) into healthcare is revolutionizing diagnostics, treatment, and patient management, but it also brings to the forefront critical ethical and legal questions surrounding informed consent. [1] This article analyzes the evolving consent requirements for AI healthcare applications, offering guidance for healthcare professionals on ethically and legally integrating these technologies into their practice.

Rethinking Informed Consent for AI

Informed consent, a foundational principle in medical ethics, mandates that patients receive adequate information to make autonomous decisions about their medical care. [2] The introduction of AI, especially "black box" algorithms, complicates this. The challenge is providing meaningful information when clinicians may not fully understand the AI's workings, undermining informed consent. [3]

Core Components of an AI-Inclusive Consent Process

Enhancing Transparency and Explainability

Transparency in AI healthcare means providing patients with clear information about the AI system, including its purpose, data processing, limitations, and potential for error. "Explainability"—articulating the AI's rationale to a non-expert—is paramount. [4]

Safeguarding Patient Data and Privacy

AI systems in healthcare are data-intensive, raising privacy and security concerns. The consent process must address how patient data will be used, stored, and protected, including for secondary purposes like research, for which separate consent should be obtained. [5] Adherence to regulations like GDPR and HIPAA is a minimum requirement. [6]

Fostering Shared Decision-Making

AI should be a supportive tool that enhances the healthcare team's capabilities and facilitates collaborative patient care. Shared decision-making, where clinicians and patients make healthcare choices together, is even more critical with AI. [7]

The Path Forward: Recommendations for Healthcare Professionals

As AI use in healthcare grows, professionals must adapt their consent practices. Clear institutional policies and guidelines, informed by ethical frameworks like those from the World Health Organization, are essential. [8]

"Dynamic consent" is a promising model, giving patients ongoing control over their data and consent preferences. [9] Standardized consent forms for AI applications would also ensure patients receive consistent and comprehensive information. [10]

Conclusion

The integration of AI into healthcare offers immense potential but requires an evolution of our approach to informed consent. Prioritizing transparency, data privacy, and shared decision-making will ensure that AI aligns with medical ethics and respects patient autonomy. A collaborative effort between clinicians, patients, developers, and policymakers is crucial for a future of trustworthy, patient-centered AI in healthcare.

References

- [1] Chau, M., Rahman, M. G., & Debnath, T. (2025). From black box to clarity: Strategies for effective AI informed consent in healthcare. *Artificial Intelligence in Medicine*, 102, 102104.
- [2] Balch, J. A., Evans, B. J., Shickel, B., & Bihorac, A. (2024). The dilemma of consent for AI in healthcare. *Surgery*, 175(1), 1-3.
- [3] Pruski, M. (2024). AI-enhanced healthcare: not a new paradigm for informed consent. *Journal of Bioethical Inquiry*, 21(1), 1-10.
- [4] Schiff, D. (2019). How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?. *AMA Journal of Ethics*, 21(2), 138-146.
- [5] Moulaei, K., et al. (2025). Patient consent for the secondary use of health data in AI models. *International Journal of Medical Informatics*, 169, 105089.
- [6] The ethics of using artificial intelligence in medical research. *Kosin Medical Journal*, 39(1), 1-7.
- [7] Hurley, M. E. (2025). Patient Consent and The Right to Notice and Explanation of AI. *The Journal of Medicine and Law*, 2(1), 1-20.
- [8] World Health Organization. (2021). *Ethics and governance of artificial intelligence for health: WHO guidance*. World

Health Organization. [9] Kotsenas, A. L. (2021). Rethinking Patient Consent in the Era of Artificial Intelligence. *Journal of the American College of Radiology*, 18(1), 139-141. [10] Park, H. J., et al. (2024). Patient perspectives on informed consent for medical AI: A web-based experiment. *Digital Health*, 10, 20552076241247938.

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