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From Informed Consent to Algorithmic Consent: Evolving Data Protection Paradigms for Generative AI in Healthcare

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Abstract: The integration of Generative AI (GenAI) into clinical decision-support, diagnostics, and personalized treatment planning challenges the foundational principles of medical data protection and informed consent. Traditional informed consent, designed for human-to-human interaction and static data use, is ill-equipped to address the dynamic, opaque, and data-intensive nature of GenAI. This paper argues that the current legal and ethical framework creates a "consent gap," leaving patients vulnerable and liabilities for providers ambiguous. The study critically analyses the inadequacies of existing data protection statutes, including India's Digital Personal Data Protection Act (2023) and the GDPR and EU AI act 2024 in governing GenAI's lifecycle in healthcare. It identifies key challenges: the impossibility of pre-emptively consenting to AI's generative outputs, the lack of explainability ("black box" problem), and the complex web of liabilities between developers, healthcare institutions, and practitioners. In response, this paper proposes the conceptual and practical framework of "Algorithmic Consent." This evolved paradigm moves beyond a one-time signature to a continuous, layered, and communicative process. It necessitates transparency about the AI's function, limitations, and data provenance, coupled with dynamic patient choice regarding the level of algorithmic involvement in their care. The conclusion offers concrete policy recommendations for embedding Algorithmic Consent into medical law, thereby strengthening patient autonomy, clarifying liability, and fostering trustworthy innovation in AI-driven healthcare.

Keywords: Algorithmic Consent, Generative AI, Medical Data Protection, AI Liability, Informed Consent, Healthcare Regulation

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