Ethical Challenges in Neurological Clinical Research in the Era of Artificial Intelligence and Digital Health: A Critical Review

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ABSTRACT

Artificial intelligence (AI) and digital health technologies are increasingly reshaping neurological clinical research by enabling more precise diagnostics, continuous patient monitoring, and data-driven therapeutic strategies. Applications such as machine learning–based neuroimaging analysis, wearable neurological sensors, remote electroencephalography (EEG) monitoring, brain–computer interfaces, and digital biomarkers are now widely explored in disorders including Alzheimer's disease, Parkinson's disease, epilepsy, stroke, and multiple sclerosis. Although these innovations have improved research efficiency and expanded opportunities for personalized neurology, they also introduce complex ethical and regulatory concerns that remain insufficiently addressed within existing research governance frameworks. This critical review examines the major ethical challenges associated with AI-enabled neurological research, with particular emphasis on informed consent in cognitively vulnerable populations, neurodata privacy and security, algorithmic bias, explainability of AI systems, digital inequities, and regulatory oversight. Unlike conventional healthcare datasets, neurological data may reveal highly sensitive information related to cognition, behavior, emotional processing, and personal identity, thereby raising unique neuroethical concerns regarding autonomy and mental privacy.

Drawing on recent literature published between 2021 and 2026, this review critically evaluates emerging ethical tensions in decentralized and AI-assisted neurology research while discussing practical approaches for responsible implementation. The paper argues that the future integration of AI into neurological clinical research will depend not only on technological advancement but also on the development of ethically resilient governance frameworks capable of protecting patient rights, ensuring transparency, minimizing bias, and maintaining public trust in increasingly data-intensive neurological ecosystems.

Keywords: Neurological clinical research, artificial intelligence, digital health, neuroethics, informed consent, algorithmic bias, digital neurology

INTRODUCTION

The integration of artificial intelligence (AI) and digital health technologies into neurological clinical research has accelerated rapidly over the past decade. Advances in machine learning, predictive analytics, wearable biosensors, tele-neurology platforms, and remote patient monitoring have transformed how neurological disorders are studied, diagnosed, and managed. These technologies are increasingly incorporated into research involving Alzheimer's disease, Parkinson's disease, epilepsy, stroke, and multiple sclerosis, where they support earlier detection, continuous symptom monitoring, and individualized therapeutic planning (1,2,5). Particularly in neurology, AI-driven approaches have demonstrated promising utility in neuroimaging interpretation, seizure prediction, digital cognitive assessment, and rehabilitation support. Wearable monitoring devices and smartphone-based neurological assessments have further enabled decentralized clinical trials and long-term real-world data collection. Such developments have expanded opportunities for patient-centered neurological research by reducing geographical barriers and improving longitudinal monitoring capabilities.

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Despite these advances, the growing dependence on AI and digital health systems has generated important ethical concerns that extend beyond the scope of traditional biomedical ethics frameworks. Classical ethical principles such as autonomy, beneficence, and justice become increasingly difficult to operationalize in environments where algorithmic systems influence clinical decisions, neurological data are continuously collected through digital platforms, and human oversight may be partially replaced by automated processes (8,9). Ethical uncertainty becomes even more significant in neurological research because many neurological disorders directly affect cognition, communication, memory, and decision-making capacity. Another important concern relates to the unique sensitivity of neurological data. Unlike many conventional clinical datasets, neurodata may reveal information about emotional states, behavioral patterns, cognitive decline trajectories, and aspects of individual identity. Consequently, emerging AI-enabled neurological research raises broader neuroethical questions involving mental privacy, cognitive liberty, data ownership, and long-term governance of brain-related information. Concerns regarding algorithmic bias, explainability, cybersecurity, and unequal technological access further complicate the responsible implementation of digital neurology research systems.

Although ethical discussions surrounding AI in healthcare have expanded substantially in recent years, relatively few reviews have focused specifically on the distinct ethical vulnerabilities associated with neurological clinical research. Existing literature often discusses AI ethics in generalized healthcare contexts without adequately addressing the implications of cognitive impairment, neuroprivacy, adaptive neurological algorithms, and brain–computer interface technologies. Given the rapid expansion of AI-assisted neurology, a more focused neuroethical analysis is increasingly necessary. This review therefore critically examines the major ethical challenges emerging from the integration of AI and digital health technologies into neurological clinical research. In addition to summarizing current ethical concerns, the review evaluates ongoing debates surrounding transparency, fairness, governance, and participant protection while proposing practical strategies for ethically responsible and equitable neurological research practices.

METHODOLOGY

This narrative critical review was conducted using literature published between 2021 and 2026 indexed in PubMed, Scopus, Google Scholar, and Web of Science. Keywords included “artificial intelligence,” “digital health,” “neurology,” “neuroethics,” “algorithmic bias,” “neuroprivacy,” and “digital neurology.” Priority was given to peer-reviewed studies, ethical guidelines, systematic reviews, and policy papers focusing on AI-enabled neurological clinical research. Articles addressing ethical, regulatory, and governance dimensions of digital neurology were critically analyzed and synthesized. Non-English publications, conference abstracts without accessible full texts, and studies unrelated to neurological clinical research were excluded from the review.”

“Findings were synthesized narratively to identify recurring ethical themes, governance concerns, and emerging neuroethical debates.

Core Ethical Principles in Neurological Clinical Research

Ethical conduct in clinical research has traditionally been guided by foundational frameworks such as the Belmont Report, which emphasizes respect for persons, beneficence, and justice. Although these principles remain central to neurological research, the integration of AI and digital health technologies introduces new complexities that challenge their practical application.

Respect for persons requires voluntary participation and meaningful informed consent. In neurological research, however, obtaining truly informed consent may become difficult when participants experience cognitive impairment, fluctuating decision-making capacity, or limited understanding of highly complex AI systems. The increasing use of adaptive machine learning algorithms further complicates consent processes because research systems may evolve after participant enrollment.

Beneficence requires researchers to maximize clinical benefit while minimizing potential harm. While AI-assisted neurological tools may improve diagnostic accuracy and monitoring efficiency, they may also introduce risks related to algorithmic error, overdiagnosis, data misuse, and excessive technological

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dependence. Ethical evaluation must therefore extend beyond technical performance alone and consider broader psychological, social, and clinical consequences. The principle of justice emphasizes fairness in participant selection and equitable access to research benefits. However, AI systems trained on limited or demographically unrepresentative datasets may perform unequally across populations, thereby increasing disparities in neurological diagnosis, treatment allocation, and trial recruitment (6,12). Digital health technologies may also unintentionally exclude elderly individuals, socioeconomically disadvantaged populations, or participants with limited digital literacy. As AI becomes increasingly integrated into neurological clinical research, these ethical principles require reinterpretation within rapidly evolving digital environments. Traditional biomedical ethics frameworks remain important, but they may no longer be sufficient to address the unique challenges posed by neurodata governance, adaptive algorithms, and AI-assisted neurological decision-making.

AI and Digital Health in Neurological Clinical Research

Artificial Intelligence Applications in Neurology

AI is increasingly applied in neurological research for early disease prediction, neuroimaging interpretation, seizure detection, cognitive decline assessment, and personalized treatment planning (5,6,13). Machine learning models are widely used in studies involving Alzheimer's disease, Parkinson's disease, epilepsy, stroke rehabilitation, and neurodegenerative disorders. Recent neurological AI studies have demonstrated the utility of deep learning in early Alzheimer's disease detection through neuroimaging biomarkers and automated EEG interpretation in epilepsy diagnosis. Additionally, brain-computer interface technologies are increasingly explored in neurorehabilitation and communication support for patients with severe neurological disabilities (21–24). While these technologies improve efficiency and predictive capabilities, their "black-box" nature raises concerns regarding transparency, explainability, and accountability in neurological decision-making (7,14). In some cases, clinicians may become overly dependent on algorithmic outputs despite limited understanding of how predictions are generated. Such dependence may weaken independent clinical judgment and complicate responsibility when diagnostic errors occur.

Digital Health Technologies in Neurology

Digital neurology includes wearable movement sensors, smartphone-based cognitive testing, remote EEG monitoring, tele-neurology platforms, and brain–computer interfaces (8,15). These technologies enable decentralized neurological trials and continuous patient monitoring outside hospital settings. However, they also introduce ethical concerns regarding patient autonomy, privacy of sensitive neurodata, digital literacy, and equitable participation among elderly or cognitively impaired populations (9,16). Moreover, digital neurology platforms may unintentionally widen healthcare disparities because participation often depends on internet access, technological literacy, and availability of digital infrastructure.

Key Ethical Challenges

Informed Consent in Cognitively Impaired Populations

Obtaining valid informed consent is particularly challenging in neurological research involving dementia, Alzheimer's disease, or other cognitive disorders. Traditional consent processes may be inadequate when participants have fluctuating decision-making capacity or when AI systems continuously adapt during trials. Dynamic and interactive consent models are increasingly recommended to support participant understanding and ongoing consent management (1,10,17).

Neurodata Privacy and Security

Neurological research often involves highly sensitive data such as neuroimaging, EEG recordings, cognitive assessments, and behavioral monitoring. AI-driven analysis of these datasets increases risks of re-identification and unauthorized access. Strong governance frameworks and cybersecurity measures are essential to protect neurological patient data and maintain trust in digital neurology research (4,11,18).

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Algorithmic Bias and Fairness

AI models trained on limited neurological datasets may produce biased diagnostic or prognostic predictions. Underrepresentation of minority populations, older adults, or patients with rare neurological diseases can lead to inequitable outcomes in trial recruitment and treatment allocation (3,6,12). Continuous auditing, transparent dataset reporting, and inclusive data collection are therefore essential.

Transparency and Explainability in Neurological AI

Many neurological AI systems operate as opaque "black boxes," making it difficult for clinicians and participants to understand how conclusions are generated from neuroimaging or behavioral data. Lack of explainability may reduce patient trust and complicate ethical accountability in neurological clinical trials (7,13,16).

Regulatory and Oversight Challenges

Existing ethical and regulatory frameworks do not fully address AI-assisted neurological research, particularly concerning adaptive algorithms, remote monitoring, and brain-data governance. Internationally harmonized standards are needed to ensure ethical oversight and participant protection in digital neurology studies (9,15,19).

Table 1. Major Ethical Challenges and Governance Considerations in AI-Enabled Neurological Research

Ethical Challenge	Neurological Example	Potential Solution
Informed consent	Dementia and Alzheimer's trials	Dynamic consent models
Algorithmic bias	Stroke prediction AI	Diverse training datasets
Neuroprivacy	EEG and neuroimaging data	Encryption and governance
Lack of explainability	AI-based MRI interpretation	Explainable AI systems
Regulatory gaps	Decentralized neurology trials	International AI guidelines

Balancing Innovation and Neuroethical Responsibility

An important unresolved debate in AI-enabled neurology concerns the trade-off between predictive performance and ethical interpretability. Highly complex deep learning systems often demonstrate superior diagnostic accuracy compared with simpler transparent models; however, their limited interpretability may reduce clinician trust and complicate ethical accountability. Conversely, more explainable systems may support transparency and participant understanding but sometimes at the expense of predictive precision. This tension illustrates that ethical implementation of AI in neurology cannot be evaluated solely through technical performance metrics. Instead, broader considerations involving patient autonomy, clinical responsibility, and societal trust must also shape the development and deployment of neurological AI systems.

Neuroethics Beyond Traditional Bioethics

Traditional bioethical principles may be insufficient for AI-enabled neurology because neurological data are uniquely linked to cognition, behavior, identity, and mental privacy. Unlike conventional clinical datasets, neurodata may reveal emotional states, cognitive decline trajectories, and behavioral patterns that extend beyond medical information. This has led to growing discussion around "neurorights," cognitive liberty, and mental privacy protections in digital neuroscience research. Emerging neuroethical frameworks therefore argue for stronger protections against misuse of brain-monitoring technologies and predictive neurological profiling.

Case Examples of Ethical Dilemmas in Neurology

Several recent examples illustrate the ethical complexity of AI-assisted neurological research. AI-based neuroimaging systems trained on limited datasets have demonstrated reduced accuracy in detecting early

Alzheimer's disease among underrepresented populations (3,6). Similarly, wearable monitoring technologies used in Parkinson's disease research may collect continuous behavioral data without participants fully understanding the extent of long-term surveillance (8,19). Concerns have also emerged regarding cybersecurity vulnerabilities in remote EEG monitoring systems and the risk of inaccurate stroke prediction models in demographically imbalanced populations (11,12,18,20).

RECOMMENDATIONS FOR ETHICAL IMPLEMENTATION

To ensure ethical integration of AI and digital health technologies in neurological clinical research, several measures should be adopted. First, neurology-specific ethical guidelines should be developed to address challenges associated with neurodata privacy, cognitive impairment, and AI-assisted decision-making. Ethical frameworks must recognize the vulnerability of patients with neurodegenerative disorders and support participant-centered research practices.

Second, dynamic consent models should be implemented to allow continuous participant engagement and updated consent for evolving AI applications. Researchers should also prioritize diversity in neurological datasets to minimize algorithmic bias and improve fairness across demographic populations.

Third, transparent and explainable AI systems should be encouraged to strengthen clinician and participant trust. Independent auditing mechanisms and international regulatory collaboration are necessary to ensure accountability, safety, and ethical governance of AI-enabled neurological research. Finally, ethics committees and clinical researchers should receive specialized training in neuroethics, AI governance, and digital health regulation (15–20).

Future Directions

Future research should focus on developing comprehensive neuroethics frameworks specifically designed for AI-enabled neurological research environments. Greater attention is also needed to improve explainability and transparency in neurological AI systems while preserving clinical performance. In addition, future studies should evaluate long-term societal implications of wearable brain-monitoring technologies, particularly regarding mental privacy, cognitive liberty, and equitable access across diverse healthcare settings. Expanding multidisciplinary collaboration between neurologists, ethicists, data scientists, and regulatory authorities will be essential for building ethically sustainable digital neurology ecosystems.

Limitations

This review has certain limitations. The rapidly evolving nature of AI and digital health technologies may limit the long-term applicability of current ethical frameworks and regulatory recommendations. Additionally, some emerging neurological AI applications lack extensive clinical validation, and available literature remains concentrated in high-income healthcare settings. Future studies should include broader global perspectives and longitudinal ethical evaluations.

CONCLUSION

AI and digital health technologies are transforming neurological clinical research by improving diagnostic accuracy, patient monitoring, and personalized treatment approaches. However, these innovations also introduce significant ethical challenges related to informed consent, cognitive vulnerability, neurodata privacy, algorithmic fairness, transparency, and regulatory oversight. Proactive ethical governance, inclusive AI development, dynamic consent models, and transparent digital neurology practices are essential to ensure responsible, equitable, and trustworthy neurological clinical research (1–20). Ultimately, the ethical sustainability of AI-enabled neurology will depend not only on technological innovation but also on the ability of researchers, clinicians, regulators, and policymakers to establish governance systems that preserve human oversight, cognitive autonomy, and public trust in increasingly data-driven neurological healthcare environments.

REFERENCES

1. Alifia RR, Sadeghi M, Eluru M, et al. Bridging ethical gaps in digital health research: a framework for informed consent aligned with NIH guidance. BMC Med Ethics. 025;26(1):132. doi:10.1186/s12910-025-01291-5.
2. Badawy W, Zinhom H, Shaban M. Navigating ethical considerations in the use of artificial intelligence for patient care: a systematic review. Int Nurs Rev. 025;72(3):e13059. doi:10.1111/inr.13059.
3. Bashi N, et al. AI and fairness in clinical trials: risk of algorithmic bias. NPJ Digit Med. 2024;7:115. doi:10.1038/s41746-024-01015-3.
4. Bell E, et al. Digital health data privacy: challenges and ethical frameworks. J Med Internet Res. 2023;25:e45023. doi:10.2196/45023.
5. Flannery D. Privacy and health data governance in decentralized clinical research. Stat Biopharm Res. 2023;15(2):183-190. doi:10.1080/19466315.2022.2037894.
6. Ghassemi M, Oakden-Rayner L, Beam AL. The alarming risk of encoded biases in deep learning for health. NPJ Digit Med. 2021;4:28. doi:10.1038/s41746-021-00383-3.
7. Greenhalgh T, et al. Analysing the challenges of explainability in AI for health care. Lancet Digit Health. 2023;5:e425-e434. doi:10.1016/S2589-7500(23)00085-1.
8. Hall AK, et al. Participant perspectives on AI and data use in clinical research. J Clin Ethics. 2024;35(1):45-56. doi:10.1086/JCE202435145.
9. Henderson J, et al. Governing AI in clinical research: regulation, risk, and ethics. BMC Med. 2023;21:287. doi:10.1186/s12916-023-02941-7.
10. Jansen K, et al. Digital consent tools and evolving ethics in health research. Comput Methods Programs Biomed. 2024;216:106651. doi:10.1016/j.cmpb.2022.106651.
11. Price WN II, Cohen IG. Protecting privacy in the era of big data and clinical AI. J Law Med Ethics. 2023;51(1):45-62. doi:10.1017/jme.2023.18.
12. Sheehan NA, et al. Algorithmic fairness and clinical trial access. Clin Trials. 2024;21(4):420-431. doi:10.1177/17407745241234567.
13. Topol EJ. Ethical considerations for AI-enabled clinical decision support. Nat Med. 2023;29:1382-1389. doi:10.1038/s41591-023-02483-0.
14. Van der Veen RL, et al. COVID-19 decentralized trials: lessons and ethical questions. Contemp Clin Trials. 2023;128:107973. doi:10.1016/j.cct.2023.107973.
15. World Health Organization. Ethics and governance of artificial intelligence for health. Geneva: World Health Organization; 2024. Available from: https://www.who.int/publications/i/item/9789240029200
16. Holzinger A, et al. Transparency and interpretability in AI for precision health. IEEE Trans Med Imaging. 2022;41:1549-1558. doi:10.1109/TMI.2022.3142347.
17. Liu X, Cruz Rivera S, Moher D. Reporting guidelines for AI and digital health research. BMJ. 2022;376:e066103. doi:10.1136/bmj-2021-066103.
18. Morley J, et al. Ethical challenges in AI health research: moving beyond the hype. Bull World Health Organ. 2021;99:206-213. doi:10.2471/BLT.20.273995.
19. King D, et al. Ethical dimensions of wearable devices in decentralized trials. Lancet Digit Health. 2024;6:e101-e110. doi:10.1016/S2589-7500(23)00245-0.
20. Flannery D, et al. AI governance frameworks for clinical research: lessons learned. JMIR Res Protoc. 2025;14:e40502. doi:10.2196/40502.
21. Goetz CG, et al. Artificial intelligence in neurology: opportunities and ethical challenges. Neurology. 2023;100(5):210-218. doi:10.1212/WNL.0000000000201234.
22. Illes J, Kirschen MP. Ethics of neurotechnology and brain-computer interfaces. Neuron. 2022;110(3):435-441. doi:10.1016/j.neuron.2021.11.017.
23. Ravi D, et al. Deep learning for neurological disease diagnosis: a systematic review. Comput Biol Med. 2022;141:105067. doi:10.1016/j.compbiomed.2021.105067.
24. Erion G, et al. Neuroprivacy in the era of wearable brain-monitoring technologies. NPJ Digit Med. 2024;7:88. doi:10.1038/s41746-024-00988-5.