DOI: 10.21088/ip.2347.1506.13225.4

International Physiology
Volume 13 Number 2 July - December 2025

REVIEW ARTICLE

AI as the Ethical Watchdog: Transforming Oversight in Medical Research

Yogesh Kumar[1], Nirangjhana Sivasubramanian[2], Saran A. K[3]

HOW TO CITE THIS ARTICLE:

Yogesh Kumar, Nirangjhana Sivasubramanian, Saran A. K. AI as the Ethical Watchdog: Transforming Oversight in Medical Research. Int.Phy. 2025; 13(2): 97–103.

ABSTRACT

Medical research is a cornerstone of healthcare advancement, but ensuring its ethical compliance remains a persistent challenge. As research methodologies grow increasingly complex, traditional oversight mechanisms struggle to keep pace. The integration of Artificial Intelligence (AI) into ethical oversight processes has emerged as a potential solution to enhance efficiency, accuracy, and consistency in ethical review. This paper explores the role of AI in identifying and addressing ethical concerns, including bias in research design, informed consent violations, and data privacy breaches.

A comprehensive analysis of AI applications in ethical review highlights its potential in protocol evaluation, bias detection, consent form analysis, and privacy protection. Case studies suggest that AI-driven tools can improve the speed and standardization of ethical reviews, reducing human workload while identifying ethical violations more effectively. However, challenges such as algorithm bias, integration difficulties, and ethical concerns regarding automation must be addressed to ensure responsible implementation.

Despite its transformative potential, AI should complement rather than replace human oversight in ethical review processes. A balanced approach, integrating AI with human expertise and robust governance frameworks, will be essential for maximizing its benefits while mitigating risks. Addressing technical and ethical challenges will be crucial in harnessing AI to strengthen ethical compliance in medical research.

KEYWORDS

• Ethical Oversight • Artificial Intelligence (AI) • Research Integrity • Governance Frameworks • Human-AI Collaboration • Ethical Risk Assessment

AUTHOR'S AFFILIATION:

[1] Professor, Department of Physiology, All India Institute of Medical Sciences, Patna, Bihar, India.

[2] Senior Resident, Department of Physiology, All India Institute of Medical Sciences, Patna, Bihar, India.

[3] Senior Resident, Department of Physiology, All India Institute of Medical Sciences, Patna, Bihar, India.

CORRESPONDING AUTHOR:

Nirangjhana Sivasubramanian, Senior Resident, Department of Physiology, All India Institute of Medical Sciences, Patna, Bihar, India.

E-mail: snirangjhana@gmail.com

➢ **Received:** 09-04-2025 ➢ **Accepted:** 10-07-2025

INTRODUCTION

Ethical considerations in medical research ensure participant protection and scientific integrity.[1] The evolution of ethical governance can be traced back to the Hippocratic Oath, formalized in the 20th century following notorious ethical violations. Landmark developments such as the Nuremberg Code (1947), the Declaration of Helsinki (1964), and the Belmont Report (1979) established foundational principles like voluntary consent, risk minimization, and justice.[2]

With the advent of genomics, big data, and international clinical trials, modern regulatory frameworks such as the Common Rule (1991, revised 2018), General Data Protection Regulation (GDPR), and Good Clinical Practice (GCP) have sought to uphold ethical standards.[3] However, as research methodologies rapidly evolve from large-scale clinical trials to complex genomic and multi-omics studies ensuring ethical compliance has become increasingly difficult.[4] Traditional ethical review processes, typically conducted by institutional review boards (IRBs) or ethics committees, often face significant challenges, including resource constraints, inconsistencies in decision-making, and the overwhelming volume of modern research data.[5]

The Evolution of Ethical Oversight in Medical Research

Ethical oversight in medical research has evolved significantly over time, responding to historical ethical violations and the increasing complexity of modern research methodologies. The early 20th century saw minimal regulatory intervention, leading to unethical studies such as the Tuskegee Syphilis Study. In response, international ethical codes and national regulations emerged, including the Nuremberg Code and the Belmont Report, to establish fundamental principles of ethical research.[6]

In India, ethical oversight follows a decentralized model requiring institutional ethics committee (IEC) approval for each research site. The Central Drugs Standard Control Organization (CDSCO) has strengthened IEC regulations, mandating their registration and enhancing their role in monitoring ongoing research, adverse drug reactions, and compliance reporting. Ethical committees now play a critical role in ensuring research integrity, informed consent, and participant safety, highlighting the increasing importance of structured ethical review in clinical trials. Despite these advancements, challenges remain in maintaining consistency, efficiency, and fairness in ethical review, paving the way for AI integration as a potential solution.[7]

Principles of Ethics in Research Involving Human Subjects

The principles of ethics in research involving human subjects rest on six core pillars: autonomy, beneficence, justice, nonmaleficence, confidentiality, and honesty. Autonomy ensures participants' rights to self-governance, informed consent, and voluntary participation. Beneficence and nonmaleficence require maximizing benefits while minimizing harm, ensuring risk-benefit balance in research. Justice mandates fair treatment and equitable risk distribution among participants, preventing exploitation. Confidentiality safeguards study data, participant records, and biological samples, ensuring privacy. Honesty obligates researchers to maintain transparency with participants, regulatory bodies, and ethics committees regarding protocols, risks, and adherence to guidelines.[8]

Ethics committees serve as the guardians of research integrity, ensuring compliance with GCP and national regulations. In India, CDSCO has mandated that only registered ethics committees can approve clinical trials, reinforcing their critical role. The committees should have diverse representation, including medical professionals, legal experts, social scientists, ethicists, and laypersons, to ensure balanced decision-making.[2]

The emergence of artificial intelligence (AI) presents a transformative opportunity to enhance ethical oversight in medical research. Advanced AI systems can efficiently process vast datasets, detect subtle ethical risks, and automate complex analytical tasks with greater precision than traditional methods.[9] Leveraging breakthroughs in natural language processing and machine learning, AI has the potential to streamline ethical review processes, improve compliance monitoring, and support more consistent decision-making.[10] This paper aims to evaluate the current state of AI implementation in research ethics oversight, analyze the effectiveness of

AI-based ethical monitoring systems, identify key challenges and limitations in AI-assisted ethical oversight, and propose frameworks for the optimal integration of AI in ethical review processes.

Traditional Approaches and Their Limitations

Traditional ethical oversight in medical research relies primarily on human reviewers who evaluate research protocols, consent forms, and ongoing study compliance.[11] While this approach has been the backbone of research ethics, it faces significant challenges that hinder its effectiveness. Resource constraints are a major issue, as limited reviewer availability and time- intensive processes slow down approvals, especially with the increasing complexity of modern research protocols.[12] Furthermore, ethical review outcomes can vary due to subjective interpretations of guidelines, differences in reviewer expertise, and inconsistent institutional standards, leading to discrepancies in decision-making.[13] Additionally, the sheer scale and volume of contemporary research projects, particularly multi-site and international studies, have added another layer of complexity. The growing amount of data collection and the intricacy of modern clinical trials make it increasingly difficult for traditional oversight mechanisms to maintain thorough and efficient review processes.[14]

The Need for Enhanced Oversight

Recent studies indicate that traditional oversight mechanisms fail to detect approximately 15-20% of potential ethical issues, particularly in large-scale and multi-site studies.[15] This gap underscores the urgent need for more advanced oversight systems capable of handling the growing demands of medical research. Without enhancements to current processes, critical ethical violations may go unnoticed, potentially compromising participant safety and research integrity. AI-powered solutions offer a promising approach to strengthening ethical oversight by addressing these gaps more efficiently than human reviewers alone.

Potential AI Applications in Ethical Oversight

A. AI in Protocol Review and Bias Detection

AI technologies are increasingly being integrated into ethical oversight processes to enhance efficiency and accuracy. One of the key applications is protocol review and analysis, where AI systems can assess research methodologies for consistency, identify potential risks to participants, ensure the inclusion of appropriate safety measures, and evaluate statistical power and sample size adequacy.[13] Machine learning algorithms play a crucial role in bias detection by identifying demographic representation issues, selection bias in participant recruitment, reporting bias in results presentation, and systematic errors in study design,[14] helping to mitigate ethical risks.

AI tools can analyze statistical patterns in research findings by comparing the results to previous studies and help in identifying outliers that might indicate data manipulation.[16] Real time compliance monitoring, which would be resource intensive for traditional methods could be achieved using automated auditing systems which could in turn alert investigators regarding noncompliance.[17] Ethical Oversight using AI can provide a ethical review framework which institutions can adopt for standardization. This can in turn improve research consistency, speed up approvals all the while maintaining ethical rigor.[18]

B. Natural Language Processing in Consent Form Analysis

Another important application of AI is in consent form analysis. AI-driven natural language processing tools can evaluate the readability and comprehension of consent documents, ensuring that risk disclosures are complete, aligned with protocol objectives, and culturally and linguistically appropriate.[15]

C. Privacy and Data Protection

Additionally, AI systems enhance privacy protection by monitoring participant data access patterns, detecting anomalies, verifying de-identification methods, and ensure compliance with regulatory frameworks such as GDPR (General Data Protection Regulation).[19]

These capabilities help mitigate privacy concerns while maintaining robust ethical oversight.

Case Studies in AI Implementation

Several institutions have successfully implemented AI-powered ethical review

systems, demonstrating tangible benefits. At Stanford Medical Center, the introduction of an AI-assisted ethics review system led to a 40% reduction in review time, a 25% increase in the identification of ethical issues, and improved consistency across different reviewers.[20]

Similarly, a European multi-center trial network implemented AI oversight tools across 12 countries, resulting in standardized protocol reviews, enhanced detection of protocol deviations, and improved monitoring of participant safety.[21] These examples highlight the transformative potential of AI in strengthening ethical oversight by making review processes more efficient and consistent.

CHALLENGES AND LIMITATIONS

Despite its advantages, AI-assisted ethical oversight faces several technical and ethical challenges. Algorithm bias remains a significant concern, as AI models depend on the quality of training data, which may have demographic representation gaps and cultural context limitations.[22] Additionally, integrating AI with existing institutional review systems presents difficulties, particularly regarding legacy system compatibility, data standardization, and implementation costs.[23]

From an ethical standpoint, the delegation of decision-making authority to AI raises critical questions about the balance between automation and human judgment. Ethical issues in medical research often involve complex moral judgments, contextual nuances, and human values that AI alone cannot fully comprehend. Concerns surrounding responsibility attribution and the establishment of appeal mechanisms must be addressed to ensure fair and accountable oversight.[24] Privacy considerations also pose challenges, particularly in safeguarding sensitive research data, maintaining reviewer confidentiality, and adhering to institutional privacy requirements.[25] These ethical and technical concerns must be carefully navigated to optimize the integration of AI into research ethics oversight.

Future Directions

To maximize AI's potential in ethical oversight, future developments should focus on enhancing AI capabilities, particularly in natural language understanding, pattern recognition, and sophisticated risk assessment models.[26] Improvements can also be made in fronts such as bias resistant AI models, that are trained on diverse representative datasets which would minimize algorithmic bias in ethical decision making.[27] Additionally, establishing standardized implementation frameworks can facilitate inter-institutional compatibility and scalable solutions, allowing AI-based systems to be seamlessly integrated into diverse research settings.[28] Future AI systems should be designed with transparency and accountability as core principles so as to explain why it flags ethical issues.[29] By addressing these technical and ethical challenges, AI can become a powerful tool in ensuring ethical compliance while preserving the integrity of medical research.

Policy and Governance

The integration of AI into ethical oversight requires well-defined regulatory frameworks to ensure reliability, accountability, and compliance. Establishing AI oversight standards is essential for maintaining consistency in ethical evaluations across institutions. Additionally, validation requirements must be put in place to assess AI systems' accuracy and effectiveness before deployment in critical decision-making processes. Accountability measures are equally important, as they define responsibility for AI-generated decisions, ensuring that both automated processes and human reviewers adhere to ethical and legal guidelines.[29]

Training and education are also crucial for the successful implementation of AI in ethical oversight. Ethical reviewers and institutional stakeholders must develop AI literacy to effectively interpret AI-generated insights and integrate them into decision-making processes. Proper training on system operation protocols will help users navigate AI tools efficiently; minimizing errors and ensuring that automated recommendations align with ethical principles. Furthermore, continuous improvement processes should be established to refine AI models, incorporate user feedback, and adapt to evolving ethical challenges in medical research.[30]

RECOMMENDATIONS

1) Implementation Strategy

A structured, phased integration approach is necessary to ensure a smooth transition to AI-

assisted ethical oversight. Initial pilot testing in controlled environments will help identify potential limitations and refine AI systems before broader implementation. Gradual expansion of AI capabilities should follow, allowing institutions to adapt progressively while monitoring system performance. Regular effectiveness assessments must be conducted to measure AI's impact on review efficiency, bias detection, and compliance monitoring, ensuring that implementation remains beneficial and aligned with institutional goals.[31]

Equally important is the need for a well-defined collaboration model between AI systems and human reviewers. AI should complement, rather than replace, human judgment by providing data-driven insights while leaving critical decisions to experienced ethical reviewers. Clear role definitions must be established to delineate the responsibilities of AI and human evaluators, preventing over-reliance on automated recommendations. Decision authority guidelines should be implemented to determine when human intervention is necessary, particularly in complex or ambiguous ethical cases. Additionally, quality control measures must be in place to monitor AI performance, ensuring that the system remains accurate, unbiased, and aligned with ethical principles.[32]

2) Governance Framework

A robust governance framework is essential to maintain the reliability and ethical integrity of AI- assisted oversight. Regular system audits should be conducted to evaluate AI's compliance with ethical standards, identify potential risks, and improve system reliability. Continuous performance monitoring will help institutions track AI's effectiveness in identifying ethical violations and streamlining review processes. Feedback integration mechanisms should also be established, allowing reviewers and researchers to contribute insights that enhance AI functionality and usability.[35]

Policy development is another critical aspect of AI governance. Institutions must establish standard operating procedures that define how AI systems should be used in ethical oversight, ensuring consistency in their application. Clear error-handling protocols should be developed to address situations where AI generates inaccurate or biased recommendations, enabling prompt corrective action. Additionally, update mechanisms must be in place to keep AI models current with evolving ethical guidelines, regulatory changes, and new research methodologies, ensuring their continued effectiveness in overseeing medical research ethics.[36]

By implementing these structured governance measures, institutions can harness AI's potential while maintaining transparency, accountability, and adherence to ethical principles in medical research.

CONCLUSION

The integration of AI technologies into ethical oversight presents a transformative opportunity to enhance the efficiency, consistency, and comprehensiveness of research ethics review. While traditional oversight mechanisms struggle with resource constraints, variability in decision- making, and the growing complexity of medical research, AI offers solutions through automated protocol analysis, bias detection, consent form evaluation, and privacy protection. However, successful implementation requires addressing key challenges such as algorithm bias, system integration, and regulatory compliance.

Conflict of Interest

No Conflict of Interest

Author's Contributions

1) Kumar, Yogesh

Group 1 - Conception and design, Analysis and interpretation of data

Group 2 - Drafting the article, Critical revision of the article

Group 3 - Final approval of the version to be published.

2) Sivasubramanian, Nirangjhana

Group 2 - Drafting the article, Critical revision of the article

3) Saran, A K,

Group 1 - Conception and design, Acquisition of data, Analysis and interpretation of data.

Group 2 - Critical revision of the article.

Group 3 - Final approval of the version to be published.

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