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Guiding Ethical Review of AI Applications in Health Research: A Ugandan Perspective

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Abstract

Artificial intelligence (AI) is increasingly being applied in health research in Uganda, offering the potential to analyze data instantly and enhance diagnostic accuracy. However, the country currently lacks formal ethical guidelines for conducting AI-driven research. Evidence suggests that ethics committees are often under-resourced, undertrained, and lack the necessary expertise to adequately assess the unique risks posed by AI in health studies. In response, this study aimed to develop a structured framework to guide the ethical evaluation of AI system development in Uganda's health research landscape. Between March and October 2024, this study utilized an exploratory qualitative design, engaging 35 stakeholders from two public universities in Uganda. Data were collected through in-depth interviews with twelve ethics committee members experienced in reviewing AI research protocols, six bioethicists, eight health researchers, and nine participants from AI development teams. The findings were analyzed using a thematic approach to identify key patterns and insights. Analysis of the data revealed six key themes: enhancing social value and equity; safeguarding the autonomy and safety of participants and end-users; addressing challenges related to data collection, access, and sharing; ensuring responsible data usage and minimizing unnecessary data retention; promoting ethical AI practices; and encouraging collaborative partnerships. Participants highlighted the potential of AI to advance health research but emphasized that its effective and safe application requires careful attention to ethical principles to protect both participants and end-users. Overall, participants believed that creating a structured guide for the ethical review of AI research could help mitigate potential risks associated with the use of AI tools in health studies. The study further recommends providing targeted training for ethics committees to enhance their understanding of the critical ethical considerations involved in developing responsible AI applications.

Keywords: Artificial intelligence (AI), Health, Uganda, Application

Introduction

The high prevalence of both communicable and non-communicable diseases, combined with limited healthcare infrastructure, has driven the adoption of advanced technologies, including artificial intelligence (AI), to enhance healthcare delivery and research. AI involves the creation of computer systems capable of mimicking human intelligence, allowing machines to learn, reason, and make decisions. In healthcare, AI is used to support accurate diagnosis, optimize treatment planning, and improve administrative efficiency. By analyzing large datasets through sophisticated algorithms, AI can detect patterns, generate predictions, and offer actionable recommendations. For instance, AI can interpret medical imaging, forecast disease outbreaks, or tailor patient care, offering the potential for faster, more precise diagnoses, lower healthcare costs, and broader access to services, particularly in underserved regions.

Despite these benefits, there is a lack of locally adapted guidance on the ethical conduct of AI health research, especially in low-resource settings. Researchers and

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organizations have increasingly recognized that AI applications raise significant ethical concerns, which can potentially harm participants and end-users. Current discussions on ethical AI highlight critical issues such as fairness, inclusivity, accountability, and the absence of clear regulatory frameworks. The development of AI systems depends on large, representative datasets to ensure that the populations likely to benefit are adequately considered. However, data owners often raise concerns about the secondary use of their information—such as for AI development or research—without their informed consent. The use of personal data by unknown third parties without consent may also compromise privacy and confidentiality.

In many developing countries, including Uganda, the use of AI in health research is still nascent, and research ethics committees (RECs) often lack sufficient understanding of AI's capabilities, limitations, and potential impacts. Globally, RECs are tasked with overseeing research involving human participants. In Uganda, RECs primarily rely on national guidelines for human subject research, which do not address the ethical use of AI and emerging technologies. Studies have shown that many REC members possess limited knowledge on how to review AI-focused protocols effectively, impeding their ability to provide timely, constructive feedback. Furthermore, identifying all potential risks associated with AI development can be challenging, as some ethical issues may arise only in later stages of system design and deployment.

Given the range of ethical challenges in AI development, there is growing emphasis on establishing frameworks for the responsible and trustworthy deployment of AI. Such frameworks are essential to ensure that individuals and society can benefit from AI while maintaining mechanisms for accountability and redress in case of harm. Several international institutions and policymakers have issued guidelines and ethical standards to govern AI development and implementation in health research. Research teams and AI developers typically rely on ethical theories, principles, and respect for human values to guide the creation of responsible AI systems. While international guidelines—such as the World Health Organization's Ethics and Governance of Artificial Intelligence for Health and UNESCO's Recommendation on the Ethics of Artificial Intelligence—promote safe, transparent, and accountable AI, there remains a need for context-specific guidance for low-resource settings like Uganda.

In response to this gap, the present study aimed to develop a guide to support the ethical review of AI system development in health research in Uganda. The findings are intended to inform national guidelines by highlighting key ethical considerations for the design, implementation, and deployment of trustworthy AI technologies in the country's health research sector.

Materials and Methods

Study design and setting

The research used an exploratory qualitative methodology [1-3] and was carried out at two government-supported public universities located in central and western Uganda. Participants were drawn from: The Department of Biomedical Sciences and Engineering at Mbarara University of Science and Technology (MUST) The College of Computing and Information Sciences and the College of Health Sciences at Makerere University Makerere University, established in 1922 as Uganda's pioneer higher-education institution, and MUST, founded in 1989, are both well-regarded for their strong emphasis on science, technology, and innovation through specialised academic units. The study also included experienced members of Ugandan research ethics committees (RECs) who had previously evaluated research protocols involving artificial intelligence and human subjects. Although the Uganda National Council for Science and Technology (UNCST) currently accredits 35 RECs across the country, only six of them had ever handled AI-related health research submissions, and these were predominantly based in the central and western regions. Data were collected over an eight-month period from March to October 2024.

Research team

The study was led by a multidisciplinary group that included two bioethicists (SN and ESM), one computer science expert (WW), a social scientist skilled in qualitative research design and analysis (AT), and a pair of research assistants.

Study participants

The study involved a total of 35 participants representing diverse expertise. This included eight health researchers, such as public health specialists, physicians, and medical doctors. Nine participants were professionals engaged in the creation of AI applications for healthcare and research, including data scientists, software engineers, bioinformaticians, language specialists, and data engineers. Additionally, the study recruited twelve members of research ethics committees who had experience reviewing AI-related research involving human participants in Uganda, along with six bioethicists.

Study procedure

Before beginning data collection, the research team received comprehensive training on the study protocol to ensure familiarity with its aims and procedures. Participants were approached via email, which outlined the purpose of the study and invited them to arrange an interview at a convenient time. Those who agreed to participate indicated their interest by replying affirmatively, after which they were provided with a consent form. Written informed consent was secured from all participants, with assurances that their information would remain confidential. Interviews were led by SN, AT, and a research assistant, while a note taker recorded observations and discussion points. Each interview was audio-recorded and lasted approximately 30 to 40 minutes.

Research tools

To develop the interview framework, the team drew upon scholarly work on AI ethics and governance [4-11]. A preliminary version of the guide was tested with a small group of three researchers and two ethics committee members, who were not part of the main study; insights from this pilot were used to enhance the questions. After each interview, the research team held reflection sessions to capture additional viewpoints not anticipated in the original guide. Interviews continued until no new themes or ideas emerged.

Data analysis

Throughout the study, data were analyzed in parallel with collection using a thematic methodology [12, 13]. All interviews were transcribed verbatim, and each transcript was carefully cross-checked with its audio recording to ensure accuracy and correct any errors. For the initial coding process, two team members (SN and AT) independently examined five transcripts line by line to generate preliminary codes. The team then met to discuss these codes, merging similar ones and resolving any discrepancies by consensus to establish a coding framework. Following this, all transcripts were imported into NVivo version 12 [14] for systematic coding by SN and AT, while WW and ESM reviewed the emerging themes to ensure consistency and reached agreement on the final thematic structure.

To verify the trustworthiness of the findings, the themes were compared against relevant literature and select transcripts were returned to participants for confirmation that their views were accurately captured. This approach strengthened both the credibility and potential transferability of the results. Key findings were summarized in **Table 1**, which presents a practical guide for the ethical review of AI system development in health research in Uganda. The coding framework was continuously refined throughout the process to reflect the final themes reported. Reporting of the study follows the Consolidated Criteria for Reporting Qualitative Research (COREQ) [15].

Table 1. Ethical review guide for AI systems in health research in Uganda

Theme	Key Considerations / Questions	Yes	No	Unclear	Notes
Advancing Social Value and Equity	• How does the AI tool or system benefit individuals or the broader community? • Does the protocol specify who will gain from the AI system and in what way? • Can the AI system contribute to social cohesion or collective well-being?				
Protecting Participant and End-User Autonomy with Human Oversight	**Informed Consent** • Have participants provided consent for secondary use of their data? • If prior consent was not obtained, is it possible to secure retrospective or prospective consent? • For data sourced from social or online media, is consent obtained beforehand? If not, does the study maximize societal benefit while safeguarding participant rights? **Privacy and Confidentiality** • Are all datasets anonymized? • Are datasets aggregated rather than individual-level? **Human Oversight** • Does the AI system allow				

	human oversight in decision-making? • How frequently will the AI tool/system be audited?
Managing Data Acquisition, Sharing, and Security	• Is the research question clearly defined to guide the selection of datasets? • Are data sources explicitly outlined in the protocol? • What measures ensure data quality? • Does the protocol comply with ethical and legal standards for data acquisition, access, sharing, and use? • Are datasets representative and inclusive of the intended beneficiaries? • What safeguards exist to protect data privacy and secure AI systems from external threats?
Ensuring Responsible Data Use and Limitation	• What strategies are in place to ensure datasets are relevant, sufficient, and limited to the research objectives?
Promoting Ethical and Accountable AI	• Does the protocol clarify ownership and accountability for AI system performance? • Are institutional procedures in place for developing safe and trustworthy AI tools? • Are AI development methods scientifically robust? • Can the team produce a detailed manual explaining system operation, result interpretation, and decision logic? • How will end-user questions be addressed in a timely manner? • What steps are taken to identify and minimize bias or discrimination? • Does the team represent diverse backgrounds (discipline, age, sex, experience)? • Are quality assurance practices adequately described?
Encouraging Collaborative Partnerships	• How does the team engage communities to gather end-user feedback, and how is it integrated into AI design? • Can AI tools be adapted into local languages, particularly for patient-facing applications? • What approaches are in place to ensure sustainability and ongoing improvement of AI products?

Developing a guide for ethical review of AI protocols
A diverse group of six specialists guided the review process, including bioethicists, a computer scientist, a software engineer, and public health experts, with four members serving on research ethics committees (RECs). Once data analysis was complete, the team carefully examined the categorized codes and illustrative quotes for each theme. Through collaborative deliberation, they developed a set of practical guiding questions intended to support RECs in the ethical evaluation of AI research protocols. These guiding questions are presented in **Table 2.**

Ethical approval for the study was granted by the Mildmay Uganda Research Ethics Committee (Ref: 0501–2024) and the Uganda National Council for Science and Technology (Ref: SS 2558ES).

Results and Discussion

Demographic characteristics
Table 2 summarizes the demographic profile of the study participants. In total, 35 individuals took part in the research, most of whom held doctoral degrees and had over ten years of experience in research.

Table 2. Demographic characteristics of study participants

Participant Group	Research Ethics Committee Members (12)	Health Researchers (8)	AI Development Team (9)	Bioethicists (6)
Highest Educational Qualification				
Master's Degree	4	3	7	4
PhD	8	5	2	2
Research Experience				
5–10 Years	5	3	6	1

More than 10 Years	7	5	3	5

Analysis of the data revealed six overarching themes: (1) enhancing social value and equity, (2) protecting the autonomy of participants and end-users while ensuring human oversight, (3) addressing challenges in data acquisition, access, and sharing, (4) promoting responsible use of data and minimizing unnecessary data collection, (5) advancing ethical and accountable AI practices, and (6) encouraging collaborative partnerships.

Promoting social value and equity

Most participants [9] emphasized that AI systems being developed should provide tangible value to end-users. They expressed particular interest in understanding who would benefit from these AI tools and in what ways. The perceived benefits were broadly categorized into individual, societal, and environmental dimensions.

At the individual level, respondents highlighted that AI could support healthcare professionals by enhancing diagnostic accuracy and improving treatment planning. They also noted that AI tools could increase efficiency, for instance by reducing the time patients spend at health facilities and mitigating the stigma associated with certain conditions. One public health specialist explained:

"Some people would benefit from AI tools, especially those with stigmatizing conditions such as HIV or mental illness. An AI system can help enroll them into studies, provide necessary information, and minimize clinic visits, limiting their exposure to public scrutiny" (IDI #10).

At the societal level, participants suggested that AI could serve the broader community by analyzing social behaviors and environmental factors to predict disease outbreaks, guide public health interventions, and improve access to health information and education. AI was also considered valuable for teaching and conducting large-scale data analyses. A data scientist noted:

"During the COVID-19 pandemic, AI models were crucial in predicting the timing of subsequent waves. This information allowed policymakers to advise the public on appropriate measures and movement restrictions" (IDI #4).

Furthermore, two software engineers highlighted that AI tools could foster social cohesion and collective problem-solving. For example, AI applications can aggregate diverse perspectives from various stakeholders to address health challenges within a community. One data engineer explained:

"I have seen AI applications that bring together different viewpoints from people affected by a disease—religious leaders, doctors, social scientists, and others—to collectively understand the problem and develop solutions" (IDI #2).

Ensuring participants and end-user autonomy and safety

Participants highlighted four main considerations regarding the protection of autonomy, safety, and well-being for both AI users and study participants.

How informed consent may be sought

Participants emphasized that obtaining informed consent for the use of clinical or research data in AI development is a fundamental ethical requirement. One bioinformatician explained:

"We typically request participants' consent for the use of their samples and data in future studies at the time of enrollment. Institutional Review Boards (IRBs) often grant waivers for secondary use of these samples or datasets by other researchers" (IDI #6).

However, respondents acknowledged the challenges of securing informed consent for data obtained from publicly accessible sources, such as social media or mass media platforms. Two bioethicists suggested that, under certain conditions, the use of such data without explicit consent could be ethically acceptable if the research poses minimal risk and offers significant societal benefits. As one bioethicist noted:

"The use of social media data has always sparked debate. Individuals have a moral right to protect their personal information, and posting it publicly does not absolve researchers of responsibility. Nevertheless, if the research has clear benefits for the community, it may be justifiable to proceed without individual consent" (IDI #24).

Protecting participants' privacy and confidentiality

The majority of respondents stressed the importance of safeguarding the privacy and confidentiality of research participants and data providers. They recommended anonymizing all data, including information sourced from publicly accessible platforms, and aggregating datasets to minimize the risk of identifying individuals.

One software developer explained: "People who share their opinions on radio programs are often unaware that this information could later be used by others, sometimes including phone numbers or personal details. To protect privacy, we anonymize the data, and even our dashboards mask names in transcripts" (IDI #19). Another developer highlighted the use of aggregated data: "To ensure participant privacy, we combine information from multiple sources to create collective datasets. Analysis and reporting are then done at the group level, rather than identifying individuals" (IDI #11).

Human oversight in decision making

While AI systems and tools can support the delivery of high-quality healthcare, respondents highlighted that these technologies should not make fully autonomous decisions regarding patients' or participants' health.

A software developer explained: "It's important to remember that machines are fallible, just like humans. The datasets and models we use are not flawless, and relying solely on AI for health decisions could have serious consequences, including death. Therefore, qualified professionals should review and verify certain results before they are applied to patient care" (IDI #5). Respondents also emphasized the need for patients and end-users to seek guidance from healthcare professionals to avoid misdiagnosis or self-medication. One bioinformatician noted: "Patients should have channels to consult clinicians before acting on treatment suggestions from AI tools such as chatbots. For instance, toll-free numbers allow direct communication with doctors, which helps prevent issues like antimicrobial resistance that may arise from self-medication" (IDI #21).

Addressing gaps in data acquisition, sharing, and security

Data needs guided by research questions

All four data scientists highlighted that the type of data required to develop AI tools is primarily determined by the research questions or study objectives. One data scientist explained: "When building AI tools, it is essential to identify the specific characteristics or features needed. We ask ourselves: what variables does the dataset include, where can we obtain this data, and how much is required to develop a robust model? These considerations are always guided by the research question" (IDI #4).

Data sources and quality considerations

Respondents indicated that they commonly use open data sources such as cloud databases, medical records, Ministry archives, online streams, radio broadcasts, and research repositories. However, one data scientist cautioned that combining datasets from multiple sources can be challenging due to differences in formatting: "Some repositories store data in complex formats, making it difficult to analyze and interpret when merged with other datasets" (IDI #7).

A software engineer further emphasized the importance of high-quality data, noting that errors such as manipulation, falsification, inequitable access, or poor coding practices could compromise AI models: "AI is like a child—it learns from the data it is fed. If the data is flawed, the resulting AI models will be biased and inaccurate" (IDI #11).

Regulatory and ethical considerations for data access and sharing

Although open data policies are increasingly promoted, respondents stressed the need for clear regulations governing the acquisition, access, and use of data. They highlighted the importance of data sharing agreements, confidentiality or non-disclosure agreements, licenses, and memoranda of understanding. One bioinformatician noted: "In Uganda, research data should only be shared under a formal agreement between the primary investigator and the receiving researcher, which must also be reviewed and approved by the REC" (IDI #3).

Data representation and completeness

Two data engineers pointed out that well-organized large datasets facilitate rapid access and integration of diverse data types for AI research. They emphasized that datasets should reflect the population of intended beneficiaries to ensure inclusivity: "Even before modeling begins, the research team must consider integrating diverse datasets to include the majority of people likely to benefit from the AI product" (IDI #1).

Ensuring data safety and security

Two REC members stressed the need for ongoing auditing of AI models to protect both data owners and end-users: "As AI technologies evolve rapidly, it is crucial to assess how prepared researchers and developers are to safeguard participant data and the outputs generated by AI tools. Regular audits are essential" (IDI #25).

A software developer added that robust security knowledge is essential to prevent unauthorized access that could harm end-users: "If AI applications are hacked or provide incorrect information, the consequences for patients could be severe" (IDI #8).

Ensuring responsible data use and data minimization

Participants highlighted the importance of using data responsibly and minimizing its scope. They identified three core principles for responsible data use: adherence to ethical standards (safeguarding individuals' rights and privacy), relevance (ensuring data is applied only for the research purpose), and adequacy (providing sufficient information to address the research question).

A software developer explained: "When considering responsible data use, several points are important. First, confidentiality must be maintained. Second, data should only be used for its intended purpose to benefit humanity. Data minimization ensures that information is handled with care and used exclusively for its original purpose" (IDI #5).

Promoting responsible AI

Respondents identified five essential principles to guide the responsible development and use of AI systems in health research.

Accountability

Several participants stressed that no AI system is flawless, similar to human decision-making, raising the question of responsibility when errors occur. Two software developers highlighted the need for clear accountability, including detailed audit trails documenting AI decision-making processes. Additionally, two REC members and one bioethicist emphasized that clearly defining ownership of AI products is critical for accountability. As one bioethicist explained: "When a machine makes a mistake, who is held responsible—the developers or the end-users? Institutions, including RECs, must ensure that AI tools are continuously monitored and that ownership and accountability are clearly defined" (IDI #30).

Transparency and openness

Transparency in AI development was seen as crucial for building trust. Three data engineers noted that developers should be accessible to answer questions about the datasets, functioning, decision-making processes, and limitations of AI tools. One data engineer stated: 'We need to be available to respond to end-users' queries about the data used, how the AI works, its decision-making process, and its limitations. Openly sharing such information fosters trust in these tools" (IDI #1).

Inclusiveness and fairness

Participants highlighted the importance of using representative and inclusive datasets to ensure AI benefits all segments of the population. Two data scientists emphasized this point, while one REC member noted the need to implement measures that minimize bias: "As a REC member, I ask whether research teams use diverse datasets and whether the techniques employed treat different groups equitably, particularly those likely to benefit from the AI tools" (IDI #31).

Many respondents also recommended assembling multidisciplinary teams and involving a wide range of stakeholders to capture diverse perspectives. A research scientist explained: "When forming my team, I considered a mix of skills and backgrounds—medical specialists, computer scientists, data scientists, language experts—as well as diversity in gender and age to promote skills sharing and mutual learning" (IDI #22).

Explainability

Most participants recognized that the technical language used in AI models is complex and not easily understood by end-users without a background in computer science. Data scientists and engineers suggested providing simple, clear explanations of AI tools' functions and outputs. As one data engineer noted: "The coding behind AI tools is not accessible to everyone, but these products are used by non-developers. We need a manual that explains each feature, the meaning of outputs, and any potential errors, all in simple, understandable language" (IDI #2).

Reliability

Respondents emphasized that cultivating trust in AI tools requires ensuring the accuracy and dependability of their outputs. One public health specialist observed: "We expect AI tools to produce accurate results. Inaccurate outputs could lead to harmful decisions, so reliability is crucial. Otherwise, we may prefer traditional diagnostic methods" (IDI #11).

Fostering collaborative partnerships

Respondents identified two critical considerations for fostering collaborative partnerships between research teams and the community during AI system development.

Community engagement

All participants stressed that meaningful engagement with communities is essential in health-related AI research. Such engagement helps build trust, raise public awareness about the role of AI in healthcare, and encourage the adoption and utilization of AI tools. Engaging communities also provides valuable insights that can be incorporated into AI design, ensures translation of AI tools into local languages, and promotes equity, particularly for populations with low literacy. A language expert explained: "Community engagement is vital to understand the languages commonly spoken in a community, enabling AI tools to be translated appropriately. When people see technologies like AI in their own language, they are more likely to use and trust them" (IDI #28).

Sustainability of AI systems

Participants offered suggestions to ensure the long-term sustainability of AI tools. One software developer emphasized the importance of continuous evaluation and iterative improvement based on user feedback: 'Even after developing the most effective models for applications, it is necessary to regularly assess and update them. Technologies evolve rapidly, and ongoing improvements are required to meet both current and future user needs" (IDI #19).

Additionally, two health researchers highlighted the value of sustained engagement with stakeholders from both government and non-government healthcare institutions to support the deployment and ongoing enhancement of AI products. As one data scientist noted: "We engage officials from the Ministry of Health, Ministry of ICT, and KCCA throughout the project. This ensures that even after the project ends, AI products can be deployed in government hospitals and continue to be improved" (IDI #4).

Toward responsible AI: ethical review guidelines for health research in Uganda

Introduction

This document serves as a practical resource for Research Ethics Committees (RECs) to guide the ethical evaluation of artificial intelligence (AI) in health research. With AI playing an increasingly central role in healthcare studies, existing review processes may not fully address the novel ethical challenges posed by these technologies. The guide offers RECs actionable considerations for assessing aspects such as transparency, data stewardship, consent procedures, fairness, accountability, and risk mitigation. By applying this guidance, RECs can help ensure that AI research is conducted responsibly, upholds participants' rights, fosters public confidence, and strengthens oversight capacity for the unique ethical issues inherent in AI-driven health innovations.

How to use the guide

This guide is intended to complement existing ethical frameworks, and Research Ethics Committees (RECs) are encouraged to tailor its use according to the specific characteristics of each research protocol. It is important to recognize that not every question will be relevant for all AI studies. Nevertheless, the guide provides a practical tool to assist RECs in evaluating protocols related to the development of AI systems in health research. It is organized around six main thematic areas identified in the study results, with each theme accompanied by a set of guiding questions for use during protocol review. Reviewers can indicate “Yes” if a theme is adequately addressed, or select “No” or “Unclear” when additional information is required from the research team. Space is also provided for written comments to justify or clarify the reviewer's decisions for each theme.

The study identified the primary ethical considerations that Research Ethics Committees should address when reviewing protocols for AI system development in health research. Based on these findings, the proposed guide is organized around six central themes, which are detailed below.

Promoting social value and equity

The application of AI in health research should prioritize equitable access, ensuring that individuals from all backgrounds can benefit from AI technologies. Key considerations include identifying how the AI tool will be used and who will gain from its implementation. Recent studies have shown that AI can enhance disease diagnosis, support effective treatment planning, improve medical education, and facilitate rapid analysis of large datasets [16-18]. However, despite these advancements, AI may inadvertently widen health disparities, particularly in low-resource settings, due to limitations such as insufficient large-scale datasets, inadequate infrastructure, and poor internet connectivity [19, 20]. Consequently, it is crucial to define the target populations and clarify how they will benefit from the AI tools. Khan and colleagues recommend comprehensive validation processes to evaluate the feasibility, applicability, and utility of AI in both research and clinical contexts. This validation should involve testing AI tools on large, diverse, and representative datasets to ensure accuracy, reliability, and equitable benefit distribution [21]. In this context, RECs should consider whether AI tools help reduce technological gaps across communities and promote social cohesion and solidarity.

Ensuring participants and end-user autonomy, safety and well being

Technological advancements in data collection, storage, and sharing have made it easier to exchange datasets globally, supporting the development of AI systems. However, this widespread sharing can pose risks to data owners, as individuals often have limited control over who accesses their information and how it is used by third parties [22]. According to Uganda's national biobanking guidelines, informed consent must be obtained from all participants providing samples or data—whether for research, clinical care, public health interventions, or surveillance—before their information is shared or used [23]. In low-resource settings, fulfilling this requirement can be challenging due to low digital literacy, difficulties in tracking participants, and problems updating contact information [24, 25]. Nevertheless, individuals retain the right to determine how their data may be used, including for future research and innovation purposes.

Key questions for ethical review include: Did participants provide consent for secondary use of their data? If not, can retrospective or prospective consent be obtained? These questions are particularly complex for publicly available data, such as social media content, where obtaining consent may be infeasible. To balance beneficence with respect for individual autonomy, RECs may consider approving studies that offer substantial societal benefits while protecting participants' rights, welfare, and interests. Furthermore, RECs should ensure that datasets used in AI development are anonymized and aggregated rather than individualized to safeguard privacy and confidentiality.

Although AI tools are increasingly applied to support research and clinical decision-making, bioethicists stress the importance of maintaining human oversight. While AI can simulate human behavior, it lacks human qualities such as empathy, moral reasoning, and compassion [26, 27]. Therefore, RECs should assess whether AI systems allow for human supervision in decision-making and ensure that these tools are subject to regular audits to protect the safety and well-being of end-users.

Addressing data acquisition, sharing, and security gaps

Researchers must carefully plan data acquisition before initiating AI projects. Respondents emphasized that clearly defined research questions and objectives are essential to determine the type of datasets needed, their sources, storage formats, and how data from multiple origins can be integrated. Ensuring that datasets represent the intended population is also critical. Biases in AI often arise from manipulated, incomplete, or poorly coded data, and many existing biomedical datasets underrepresent certain groups [28, 29]. Using such data can lead to inaccurate predictions, misdiagnoses, or inequitable healthcare delivery [30].

Ethics committees should evaluate whether researchers have outlined strategies to access sufficient, high-quality, and relevant data that mitigate potential bias. Compliance with legal and regulatory standards is also necessary; for example, the Uganda Data Protection and Privacy Regulations (2021) require that data handlers safeguard personal information [31]. Institutions should formalize data sharing agreements that clearly define responsibilities and prevent misuse, with REC oversight and approval. Additionally, developers must implement robust security measures to protect datasets and AI systems from external threats. RECs should ensure that protocols provide sufficient information on these security safeguards to prevent harm to participants and end-users.

Ensuring responsible data use and data minimization

The increasing emphasis on open access and data sharing, encouraged by funding bodies and journal policies, has led to wider availability of large-scale datasets worldwide [32, 33]. Nonetheless, issues around consent, privacy, and governance persist, especially in settings with limited resources [22]. Key questions arise, such as: "What does responsible data use and data minimization involve?" and "How can researchers handle existing data ethically?" To reduce the risk of misuse, experts have recommended limiting data collection and access to only what is necessary and directly relevant for the research objectives. For instance, Robin Staab and colleagues suggested a vertical data minimization approach, which protects privacy by avoiding the collection of high-resolution client data during AI model training and deployment [34]. Therefore, it is essential for research institutions, investigators, and research ethics committees to ensure that data collection and access strategies focus on datasets that are appropriate, necessary, and sufficient to answer the research questions.

Promoting responsible AI

From our findings, five central principles for responsible AI emerged: accountability, transparency and openness, inclusiveness and fairness, reliability, and explainability. A fundamental aspect of responsible AI is ensuring that humans, rather than machines, remain accountable for the decisions, actions, and consequences of AI systems. As respondents noted, "no AI system is flawless, just as no human is perfect." Nevertheless, pressing questions must be addressed, such as: who is held responsible for medical errors resulting from AI decisions? Who owns the AI product? And what mechanisms exist to prevent or mitigate mistakes? Clearly defining the roles and responsibilities of teams involved in designing, deploying, and operating AI systems is crucial [35]. Additionally, research ethics committees suggested that host institutions should implement oversight structures, mechanisms for redress, and routine audits. By systematically examining and documenting decision-making processes, audits allow institutions to verify that AI systems adhere to ethical, legal, and technical standards [36]. This also enables AI-generated decisions to be reviewed, interpreted, and challenged when necessary. Mokander and Floridi highlight that ethics-based auditing can enhance decision quality, boost user confidence, and unlock opportunities for improved health service delivery through automation [37].

Transparency and openness are equally vital. Developers and researchers should provide clear information about how AI systems are created and intended to be used to foster trust and accountability. This transparency helps stakeholders and end-users understand the system's purpose, design, data sources, and decision-making processes, thereby supporting public confidence and compliance with ethical and legal norms [38]. Data scientists also emphasized that platforms should allow users to ask questions and receive timely responses. Public fears—such as concerns that AI could eventually dominate humanity—are exacerbated by limited understanding of how AI functions [39]. Presenting information in clear, accessible language ensures that users of all educational backgrounds can grasp how AI works, helping to alleviate anxiety and build trust.

Inclusiveness and fairness require using datasets that represent the populations likely to benefit from AI tools, minimizing bias in outcomes. Research teams should also be multidisciplinary, incorporating members of diverse ages and experiences. This diversity allows for multiple perspectives on AI design and functionality, ultimately improving the relevance and effectiveness of AI applications for end-users in research and healthcare.

Reliability is another critical principle. Ethics committees should ensure that AI systems are designed to produce consistent, accurate, and predictable outcomes. As AI becomes increasingly integrated into health systems and research across countries, users must be confident that the results are dependable. Research institutions should implement quality assurance procedures and standard operating protocols to maintain the trustworthiness of AI-generated decisions.

Promoting collaborative partnerships

Our respondents emphasized the importance of engaging communities and stakeholders as a strategy for fostering collaborative partnerships, raising public awareness of AI's role in health research, and ensuring the long-term sustainability of AI tools. Active involvement of communities and other research stakeholders throughout the development process helps build lasting relationships grounded in mutual trust and respect [40, 41]. Such engagement encourages co-learning, transparency, and open sharing of knowledge. Communities have the opportunity to express diverse perspectives on their understanding of AI and its applications in healthcare and research, which can help correct misconceptions. Meanwhile, researchers can identify features that better meet end-user needs and determine the most accessible language and interfaces for AI tools. Regardless of the engagement approach, researchers should clearly outline the strategies for soliciting feedback and explain how this input will influence the design of AI systems. These strategies should be reviewed by research ethics committees to ensure they respect the values, interests, and dignity of participants and communities.

Regarding the sustainability of AI systems, research ethics committees and institutions should ensure that research teams develop plans for ongoing evaluation of AI tools to maintain effectiveness and user satisfaction. Given that research projects are typically time-limited, collaboration with governmental and non-governmental stakeholders should be encouraged to ensure continuity in AI tool functionality.

A major strength of this study was the involvement of stakeholders from diverse disciplines in the development of AI systems for health research, which enriched the ethical review guidance for AI research protocols. A key limitation, however, was the potential for bias due to the authors' dual roles as REC members and researchers, with SN moderating some interviews. As authors, we were conscious of the need to remain neutral, actively listening to respondents' perspectives and probing where necessary. Complete objectivity was challenging, as our experiences with RECs and AI development inevitably influenced our viewpoints. To mitigate this, we conducted protocol training and ensured that most interviews were led by an experienced qualitative researcher who was largely unknown to participants. We also created a welcoming and informal environment to encourage open and honest sharing.

Conclusion

The findings of our study highlight major thematic areas and corresponding guiding questions that research ethics committees (RECs) may consider when evaluating protocols for AI tool and system development in health research, aiming to reduce potential risks to both participants and end-users. We suggest that future studies investigate how these thematic domains are applied in practice and focus on training RECs to address the specific ethical challenges posed by AI research. Furthermore, we recommend that policymakers create research guidelines tailored to local contexts to support the responsible development and implementation of AI technologies in health research.

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