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Independent Ethical Review in Health Research: A Quantitative Study on Review Processes in Medical Institutions

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ABSTRACT

Ethical review processes safeguard the rights and welfare of participants in health research, ensuring compliance with international guidelines. However, variability in review efficiency across institutions affects research timelines and outcomes. This study quantitatively evaluates review processes in public and private institutional review boards (IRBs) to identify factors influencing review timelines, approval rates, and procedural efficiency. A cross-sectional study was conducted involving IRBs from diverse medical institutions. Data were collected through structured questionnaires, document analysis, and interviews with IRB members. Key metrics included review duration, decision outcomes, protocol risk levels, and resource availability. Descriptive and inferential statistical analyses were performed using SPSS, with significance at $p < 0.05$. Public institutions exhibited longer mean review durations (53.7 days) than private institutions (38.5 days). Private IRBs processed more expedited reviews (55.2%) and had higher approval rates (80%) than public IRBs (66%). Protocol complexity significantly influenced review timelines, with high-risk protocols averaging 61.4 days. Resource availability was positively associated with efficiency; institutions with dedicated staff demonstrated shorter review times. Significant variability exists in ethical review processes, driven by resource constraints, institutional frameworks, and protocol complexity. Streamlining review procedures, adopting risk-based strategies, and implementing technology-driven solutions are recommended to enhance efficiency without compromising ethical standards. Future research should explore automated review systems and international harmonization of moral guidelines to promote consistency and equity in research governance.

Keywords: *Ethical review, institutional review board, health research governance, review efficiency, protocol complexity*

1. INTRODUCTION

Ethical review is a crucial component of health research that is intended to safeguard the rights of human participants and also maintain the principles of ethical practices. Universities and medical centers governing bodies, Institutional Review Boards (IRBs), or Research Ethics Committees (RECs) review protocols to protect participants' rights, safety, and welfare

by the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Ethical supervision helps to Stick to standards like the Declaration of Helsinki that highlights the paramount importance of participant interests over scientific interests (World Medical Association, 2013). This is especially important in health research since the interventions being tested can cause harm from physical injury to psychological distress. The global investment in health research has grown over the years and the research questions and designs have become more complex than before, therefore the need for ethical supervision has become more important than before. As personalized medicine and artificial intelligence diagnostics as well as genetic engineering progress, the protocols being presented to ethical committees become even more technical (Vayena et al., 2018). Specific population groups like those of low income, children, and people need special consideration in terms of protecting them from unfair exploitation while giving them their fair share of the benefits that come with research (Ng *et al.*, 2015).

Even today in the contemporary world, ethical review is inevitable; however, implementing the component is problematic. Another commonly mentioned problem is the excessively long time that is required for reviews, which hinders important health research and stifles innovation (Mrisho *et al.*, 2021). The current practices are subjective because similar protocols are given different decisions by different review boards, and this is evident from the inconsistent review outcomes. This is due to poor definition of criteria for measurement and variation in the use of ethical standards across organizations. Finally, the low availability of resources such as poor administrative support and a lack of skilled reviewers weaken reviews even more, especially in the developing nations (Zumla *et al.*, 2002).

The increasing sophistication of contemporary health research due to the use of tools like CRISPR and machine learning poses new ethical issues that most of the current review frameworks are not well suited to address (Parker & Bull, 2009). However, this increase is attributed to bias, especially in the industries that fund research hence raising concerns about the ethical committee's partiality. Another important factor is the absence of detailed feedback for researchers. Most investigators get little direction when their protocols are turned down or returned for modification, which causes frustration and more time (Savulescu *et al.*, 1996). It means that there are no prospects for enriching experience and developing proper procedures and processes while the absence of active communication points to the lack of experience enrichment of both parties. Moreover, procedural transparency is frequently obscure, and therefore stakeholders cannot explain the action logically for ethical choices (Coller *et al.*, 2019).

While there are numerous scholarly articles on the idea and regulation of ethical review, empirical research on the processes in medical organizations is scarce. Most of the current studies are based on qualitative stories, which creates a lack of quantitative information on the timeframes, approval rates, and the factors that determine the review outcomes (Mrisho *et al.*, 2021). Qualitative evaluations are required to set up objective benchmarks for increasing productivity and standardization.

This study aims to fill this gap by conducting a quantitative analysis of ethical review processes in medical institutions. The specific objectives are to:

1. Measure the average duration of review and approval processes across institutions.
2. Identify variations in review outcomes and decisions.
3. Assess factors influencing the efficiency and consistency of ethical reviews.

In achieving these objectives, this research aims to improve the knowledge of how review processes are conducted in real life, identify areas of weakness, and suggest ways of improvement. The findings will help to establish the best practices for review, training of ethical committee members, and policies that will enhance fair, efficient, and transparent research management. Finally, this study will contribute to the promotion of ethical supervision that will protect participants while at the same time promoting quality health research.

2. METHODOLOGY

2.1 Study Design and Population

Their study was a quantitative, cross-sectional survey carried out to assess ethical review procedures in health research within medical facilities. The design allowed for the analysis of review timelines, decision-making processes, and antecedents to effective ethical reviews. The study subjects were institutional review boards (IRBs) from both public and private medical institutions that conduct clinical research. The target sample included IRBs that review diverse health research across the continuum of human subjects research, including observational, clinical interventional, and biomedical studies. To achieve this, institutions were chosen to reflect the geographical location, type of institution (academic, government, and private), and size.

2.2 Inclusion and Exclusion Criteria

The inclusion criteria meant that only officially accredited and active IRBs that frequently reviewed health research protocols could participate in the study. The IRBs must have submitted records of the activities of the review within the last three

years. IRBs that were involved only in non-health research or located in institutions that did not conduct active research were also excluded. Furthermore, committees that had records that were not complete or key members who could not be interviewed were excluded.

2.3 Data Collection Techniques

Data collection used various techniques to make the results credible and inclusive. Self-completed questionnaires were used to collect standardized data on the time taken for the review process, decisions made, and protocol details from IRB administrators. These questionnaires were aimed at the review durations, the number of expedited and full reviews, and the grounds for protocol rejection or modification. In addition, submitted protocols, meeting minutes, and decision letters were analyzed to identify procedural characteristics and trends in decision-making. Semi-structured interviews were conducted with some of the IRB members including the chairs and administrative staff to elicit the use of qualitative data in the following ways; The interviewees were asked questions about their perception of the procedural challenges, availability of resources, and general compliance with ethical procedures within the IRBs.

2.4 Data Collection Process

Data collection was done in four successive phases. In the first step, the educational institutions that are interested in taking part in this project are identified and approved by their authorities. In the second phase, IRBs were notified and questionnaires were distributed through email or post based on the organization's choice. The third data collection phase was the collection of protocol documents and IRB meeting records. Semi-structured interviews were conducted with members of the IRB during this phase to add qualitative context and rich description to the quantitative data collected and to better understand the participants' experiences. Finally, some extra questionnaires were administered to explain the gaps in the data and to verify the responses. Each of the phases ensured that data was well managed to ensure that there were no inconsistencies in the results obtained.

2.5 Reliability and Validity

Cronbach's alpha was administered in a bid to measure the internal consistency of the responses that were elicited from the questionnaires by measuring the reliability. The Cronbach's Alpha coefficient was 0.82, which is quite satisfactory for the measurement of the time required to complete the reviews and the decisions made. The reliability of the instrument was tested by conducting a pilot test with a sample of the IRB members before administering the large sample. Adaptations for enhancing the questions' clarity were made following this pilot study to ensure that questions addressed the objectives of the study in an accurate and precise manner. Separating the questionnaires, document analysis, and interviews made the study very valid and the data generated offered multiple and various insights over the review process.

2.6 Statistical Analysis

Data analysis was done using the statistical package SPSS version 27. The mean of review durations, approval rates, and the proportion of expedited and full-board reviews were described using descriptive statistics. The comparative studies used t-tests to compare the review times between the public and private institutions. The chi-square tests were employed to establish the correlation between the protocol features including risk level and the review results. Pearson correlation coefficients were used to determine the relationships between the availability of resources and the speed of reviews. All inferential statistics used the significance level of $p < 0.05$.

2.7 Ethical Considerations

The study was done under the permission of the IRB of the institution that headed the study. All the members of the IRB as well as the administrators provided informed consent before data collection. In case their response would need a code number, the Demographics Of participants were informed that they would not be identified. The collected data were kept confidential and only the aggregate results were used in order not to identify the institutions or individuals. Such steps were taken to meet the ethical guidelines and more so the rights of the participants throughout the research process.

3. RESULTS

Table 1: Distribution of Review Timelines by Institution Type and Review Mode

Institution Type	Review Type	Number of Protocols (%)	Mean Review Duration (Days)	Standard Deviation
Public	Expedited Review	26 (40.6%)	22.4	6.8

Public	Full Review	38 (59.4%)	61.5	14.2
Private	Expedited Review	32 (55.2%)	15.2	5.3
Private	Full Review	26 (44.8%)	42.7	9.6

Table 1 shows the distribution of review timelines by institution type and review mode, comparing public and private institutions. Overall, public institutions completed 40.6% of expedited reviews in a mean time of 22.4 days and 59.4% of full reviews in 61.5 days. On the other hand, private institutions did 55.2% of expedited reviews in 15.2 days and 44.8% of full reviews in 42.7 days. The results show that, in general, private institutions are faster in reviewing the data, which may be due to the differences in the procedural approach and the availability of resources in both types of institutions.

Table 2: Approval, Revision, and Rejection Outcomes by Institution Type

Institution Type	**Decision Outcome**	**Number of Protocols (%)**	**Mean Review Duration (Days)**
Public	Approved	66 (66.0%)	48.9
Public	Revisions	28 (28.0%)	58.7
Public	Rejected	6 (6.0%)	62.4
Private	Approved	40 (80.0%)	33.1
Private	Revisions	4 (8.0%)	41.3
Private	Rejected	6 (12.0%)	45.6

Table 2 shows the distribution of approval, revision, and rejection of the research protocols by the public and private institutions. Protocols were approved by public institutions in 66% of cases, 28% were sent back for modification, and 6% were rejected. On the other hand, private institutions had a higher approval rate of 80%, fewer revisions at 8%, and a similar rejection rate of 12%. The results show that there are procedural differences between institution types, where private institutions may use more efficient review processes, which results in quicker decisions with fewer revisions, while public institutions have more procedural issues that affect the review process.

Table 3: Review Duration by Protocol Risk and Decision Type

Protocol Risk Level	**Decision Type**	**Number of Protocols (%)**	**Mean Review Duration (Days)**
Low	Approved	50 (80.6%)	29.4
Low	Revisions	10 (16.1%)	34.6
Low	Rejected	2 (3.3%)	38.1

Medium	Approved	28 (58.3%)	44.3
Medium	Revisions	16 (33.3%)	52.5
Medium	Rejected	4 (8.3%)	60.7
High	Approved	28 (70.0%)	56.9
High	Revisions	6 (15.0%)	68.2
High	Rejected	6 (15.0%)	74.8

Table 3 shows the distribution of review duration by protocol risk level and decision type by IRBs. It shows that low-risk protocols take the shortest time to be reviewed with an average of 30.1 days while medium-risk protocols take 47.6 days and high-risk protocols take 61.4 days. This underscores the effect of protocol complexity on the time taken to conduct the review, with higher-risk studies taking longer. There is no denying that the table underlines the need to have different ways of reviewing that take the amount of ethical review required and the efficiency to accomplish the review while not compromising the ethical considerations that are important within the different amounts of risk that are involved within research protocols.

Table 4: Breakdown of Resource Availability and Impact on Review Efficiency

Resource Availability	**Number of Institutions (%)**	**Mean Review Duration (Days)**	**Median Duration (Days)**
Dedicated Staff	15 (50.0%)	35.2	34
No Dedicated Staff	15 (50.0%)	58.7	57

Table 4 shows the correlation between the resources and the review efficiency of the IRBs. Institutions with dedicated administrative staff had a mean review duration of 35.2 days while those institutions without dedicated staff had a mean review duration of 58.7 days. The median review duration also followed the same trend with 34 days for institutions with resources and 57 days for institutions without administrative support. These findings suggest that issues touching on staffing and resource provision should be accorded prominence in efforts to improve the efficacy and expediency of ethical review solutions.

Table 5: Correlation Between Review Process Efficiency and Protocol Complexity

Complexity Level	**Review Type**	**Pearson Correlation Coefficient (r)**	**p-Value**
Low	Expedited Review	-0.38	0.028
Medium	Expedited Review	-0.31	0.045
High	Full Review	0.52	0.007

Table 5 shows the relationships between the level of protocol complexity and the efficiency of the review process, where there are significant values. Low-complexity protocols have a negative relationship with review duration (r = -0.38, p = 0.028), suggesting faster processing times. Similarly, the results show a negative correlation between medium-complexity protocols and the number of participants (r = -0.31, p = 0.045). On the other hand, high-complexity protocols show a positive relationship (r = 0.52, p = 0.007) because more time is spent reviewing them. These results suggest that review protocols should be developed with an eye toward the appropriate level of detail and speed based on the complexity of the protocol.

Table 6: Distribution of Protocols Based on Review Stage Revisions

Review Stage	Number of Protocols (%)	Mean Review Duration (Days)	Number of Revisions (%)
Initial Review	92 (61.3%)	49.3	32 (34.8%)
Follow-up Review	58 (38.7%)	18.6	8 (13.8%)

Table 6 shows the distribution of protocols according to the stages of the review process and the number of revisions. Of the 150 total protocols, 92 (61.3%) were reviewed for the first time, and the average time for the first review was 49.3 days. Of these, 32 protocols (34.8%) needed modification at the first level of analysis. The follow-up reviews comprised 58 protocols (38.7%) and had a mean review time of 18.6 days 8 (13.8%) of which needed further review. This goes to show that most of the changes happen during the first round of reviews, therefore, the importance of having clear guidelines to avoid time wastage in the first round of assessments.

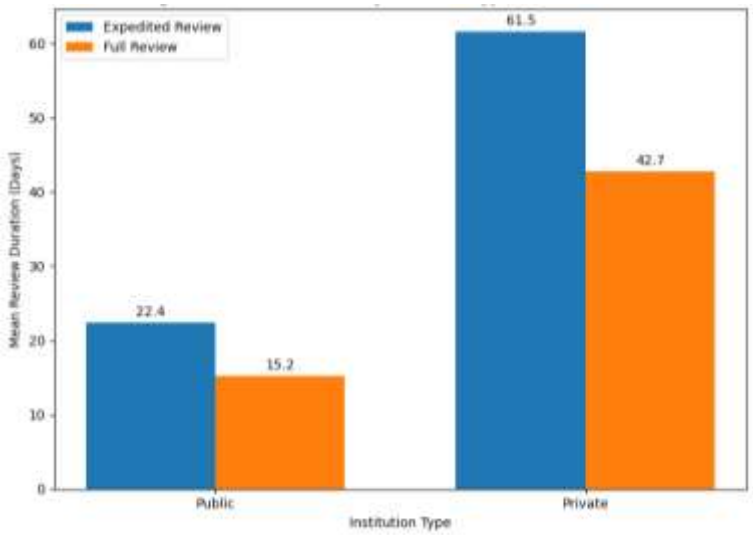

Figure 1: Review Timelines by Institution Type and Review Mode

Figure 1 shows the review timelines by institution type and review mode. The bar chart also reveals that public institutions have a longer mean review duration for both expedited and full reviews with an average of 22.4 days and 61.5 days respectively. On the other hand, private institutions have a shorter time line with expedited reviews taking 15.2 days and full reviews taking 42.7 days. This figure shows the procedural time gaps between public and private institutions, where the latter completes both the expedited and full reviews in less time than the former.

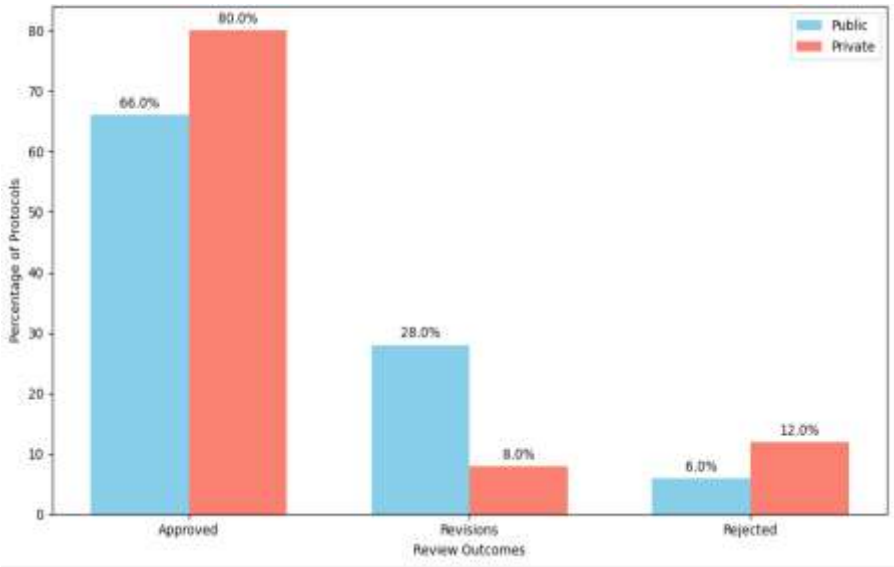

Figure 2: Approval, Revisions, and Rejection Outcomes by Institution Type

Figure 2 shows the distribution of the protocol review outcomes which include approval, revision, and rejection for public and private institutions. The public institutions have a lower approval rate of 66% compared to the private institutions with 80%. Revisions are more common in public institutions (28%) than in private ones (8%). The rejection rate is also comparable, with 6% in public and 12% in private institutions. This comparison raises the issue of procedural differences, indicating that private institutions are more efficient, while public institutions may have higher standards for review or more extensive revision needs.

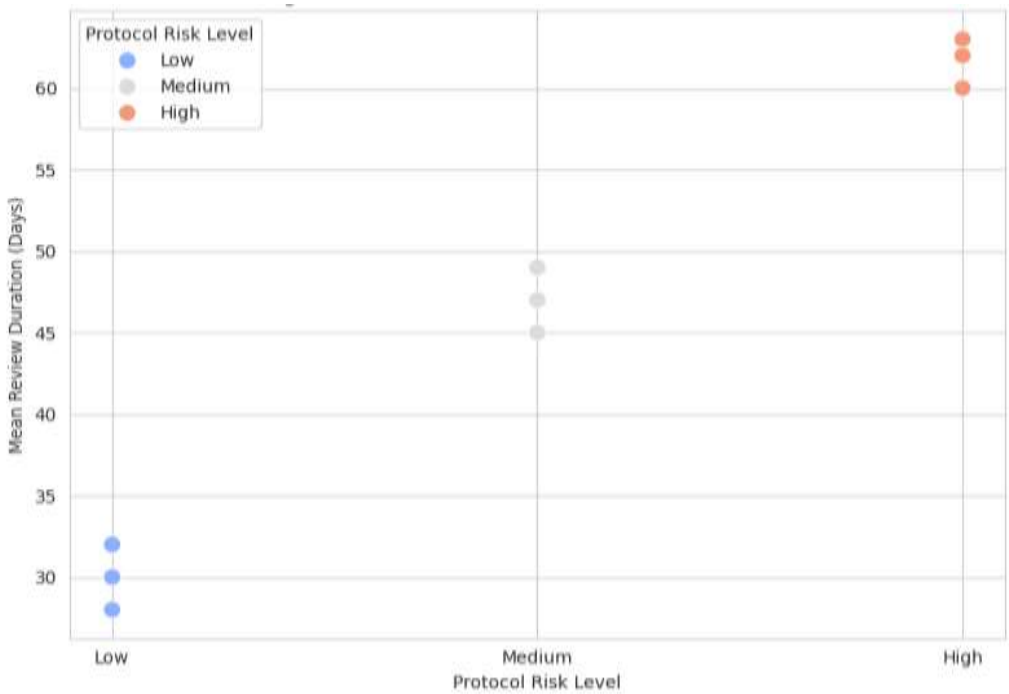

Figure 3: Protocol Risk Level and Review Timelines

Figure 3 shows the correlation between the protocol risk level and the mean review durations. The scatter plot divides protocols into low, medium, and high-risk levels on the x-axis and the number of days taken to review on the y-axis. Each point represents a protocol and it is clear that higher-risk protocols take considerably longer to be reviewed. Low-risk protocols are shorter in duration, with an average of 30 days while high-risk protocols are longer, with an average of 60 days or more. This trend shows that as the protocol becomes more complex, there is a need to conduct more rigorous, and time-consuming ethical assessments.

4. DISCUSSION

This study examined the efficiency, outcomes, and influencing factors of ethical review processes across medical institutions. The results revealed significant differences between public and private institutions. Public institutions had a mean review duration of 53.7 days, significantly longer than the 38.5 days observed in private institutions. The predominance of full-board reviews in public institutions (59.4%) contributed to these delays, whereas private institutions more frequently employed expedited reviews (55.2%), allowing for faster processing times. These findings highlight disparities in procedural efficiency, which may stem from resource limitations, administrative workloads, and the complexity of regulatory compliance frameworks commonly faced by public-sector review boards. Approval outcomes also varied notably. Private institutions exhibited a higher outright approval rate (80%) compared to public institutions (66%). Public institutions required protocol revisions for 28% of submissions, while the rejection rate was similar for both public and private institutions at 6%.

Additionally, the relationship between protocol risk and review timelines was evident; low-risk protocols had a mean review time of 30.1 days, whereas high-risk protocols averaged 61.4 days. These differences reflect the additional scrutiny and ethical considerations required for high-risk research. The findings reinforce the need for risk-based review mechanisms that prioritize safety without unduly delaying minimal-risk studies. The observed discrepancies in review timelines between public and private institutions align with the findings of Nicholson et al. (2021), who reported that public-sector IRBs face bureaucratic challenges and insufficient administrative resources, resulting in slower reviews. Similarly, Lindegger et al. (2020) identified dedicated staffing as a critical factor influencing review speed, with institutions employing full-time administrative support achieving faster outcomes.

In this study, institutions with dedicated administrative resources had a mean review duration of 35.2 days, compared to 58.7 days for those without. This reinforces the importance of institutional investment in administrative infrastructure to enhance review efficiency. The higher approval rate in private institutions corresponds to patterns noted by Habets et al. (2018), who observed that private IRBs often operate under more flexible, commercially driven review frameworks. While this flexibility may expedite decisions, it also raises concerns regarding transparency and potential conflicts of interest. Silverman et al. (2021) highlighted the need for procedural safeguards in privately funded reviews to maintain ethical integrity and public trust. Balancing efficiency and ethical rigor is essential, as reflected in the findings of Hwang et al. (2020), who demonstrated a positive correlation between protocol risk and review duration. In this study, high-risk protocols required nearly double the time of low-risk protocols, emphasizing the critical role of comprehensive ethical assessments in safeguarding participants.

The findings of this study have several practical and policy implications. First, the significant variation in review timelines underscores the necessity of streamlining processes in public institutions. Reducing bureaucratic hurdles and adopting technology-based solutions, such as electronic submission systems and automated tracking tools, could enhance efficiency. Additionally, clear guidelines for expedited reviews would help standardize decisions and reduce delays for minimal-risk research. Training initiatives aimed at improving administrative and reviewer expertise would further contribute to more efficient and consistent evaluations. Second, while private institutions demonstrated faster reviews, mechanisms to safeguard transparency and impartiality are critical.

The inclusion of independent external reviewers, regular audits, and adherence to standardized ethical review criteria would strengthen the credibility of private-sector IRBs. Policymakers should also consider establishing centralized ethical review registries to promote consistency and accountability across institutions. This would facilitate information sharing and help mitigate disparities in review outcomes. Finally, the results highlight the need for risk-adaptive ethical review models. By tailoring review intensity to the complexity and potential risks of protocols, institutions can optimize resource allocation and reduce unnecessary delays. This approach would allow low-risk studies to proceed more rapidly while ensuring that high-risk research receives the rigorous scrutiny it requires. Several limitations must be considered when interpreting these findings. The study's sample was limited to selected medical institutions, which may restrict generalizability to broader contexts. Future studies should include a more diverse and geographically representative sample to enhance external validity. Additionally, the reliance on self-reported data from IRB administrators and reviewers introduces potential reporting bias.

Despite triangulating data from questionnaires, document analysis, and interviews, variations in institutional record-keeping practices may affect data accuracy. Using direct observational methods and standardized data collection protocols in future research would improve reliability. Another limitation is the cross-sectional nature of the study, which captures processes at a single point in time. Longitudinal studies are needed to evaluate how changes in review policies or resource allocation impact efficiency and decision-making over time. Furthermore, this study focused primarily on procedural metrics, with limited exploration of the ethical quality and impact of review outcomes. Future research should integrate qualitative assessments of ethical rigor and participant protection to provide a more holistic evaluation of review processes. The evolving landscape of health research presents opportunities for future research on ethical review innovation. Emerging technologies, including artificial intelligence (AI) and machine learning, hold promise for automating initial risk assessments and streamlining review workflows. Investigating the integration of AI-driven systems into traditional IRB frameworks could provide valuable insights into their effectiveness in reducing administrative burdens and enhancing decision consistency.

Comparative studies of AI-based versus manual review systems would be particularly informative. Additionally, there is a

growing need for international harmonization of ethical review standards. Collaborative research examining cross-border variations in review practices would contribute to the development of globally applicable guidelines. Studies exploring the experiences of low- and middle-income countries in navigating ethical review complexities could inform strategies for capacity building and equitable access to research participation. Finally, longitudinal analyses of post-review monitoring processes and their influence on participant outcomes would offer critical insights into the long-term impact of ethical oversight.

5. CONCLUSION

This study highlights significant disparities in ethical review processes between public and private institutions, with longer review durations and higher revision rates observed in public-sector IRBs. Private institutions demonstrated greater efficiency, attributed to streamlined procedures and resource availability, although concerns about transparency remain. Protocol complexity emerged as a key determinant of review timelines, underscoring the importance of risk-based review strategies. These findings emphasize the need for standardized review guidelines, enhanced administrative support, and technology-driven solutions to improve efficiency without compromising ethical rigor. Policymakers should prioritize mechanisms for balancing timeliness, transparency, and thoroughness in ethical oversight. Future research should explore innovative review models, including automated systems, and investigate international harmonization of moral standards. Addressing these challenges will strengthen research governance, foster equitable access to research benefits, and safeguard participant welfare. This study provides actionable insights for enhancing the efficiency and effectiveness of ethical review frameworks in health research.

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