Editorial

Strengthening postapproval oversight in research ethics committees: Challenges and solutions

The establishment of robust ethical review processes is crucial to safeguard the rights and well-being of human subjects participating in research studies. The aftermath of historical scandals, such as the Tuskegee study, led to the development of ethical guidelines such as the Belmont Report, emphasizing the need for Institutional Review Boards and Ethics Committees. Over time, these bodies have become the golden rule for conducting human subject research, ensuring a thorough review process before initiation.[1]

As of May 26, 2023, the registration of Ethics Committees in India is carried out by regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) and the Department of Health Research (DHR). Specifically, within the CDSCO, there are currently 1505 registered Ethics Committees and 1766 Ethics Committees have undergone re-registration. Similarly, the DHR has provisionally registered 614 Ethics Committees and fully registered 278 Ethics Committees.[2,3] In addition, 187 Ethics Committees have received accreditation from the National Accreditation Board for Hospitals and Healthcare Providers.[4] India has a total of 17 registered Ethics committees, which are recognized by the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP), and only 12 of them have been renewed.[5] This multi-tiered approach, combined with the evaluation carried out by FERCAP, enhances the reliability and effectiveness of the research ethics committee (REC) framework.

While considerable attention is given to the preapproval review process, the importance of postapproval oversight is often overlooked. The continuous review of projects after approval is essential to ensure the ongoing ethical conduct of research. However, many ethics committees in India lack the mechanisms, resources, and manpower to effectively fulfill this obligation.[6,7]

To shed light on the challenges faced by ethics committee members in conducting postapproval activities, a study was conducted involving 61 member secretaries representing 61 ethics committees from 18 states across India. The study, published in this issue of the journal, utilized a questionnaire that explored the committees' functioning, challenges encountered during postapproval processes, and potential solutions to these challenges. A few limitations exist within this study. First, the small sample size of only 61 member secretaries who responded may limit the generalizability of the findings to all ethics committees in India. Second, the study primarily focuses on the perspectives of member secretaries, possibly overlooking the full spectrum of challenges faced by other committee members or research participants. Furthermore, the study's scope is restricted to examining challenges within the postapproval processes of ethics committees, neglecting other aspects of their operations, and the assessment of suggested solutions' effectiveness. Finally, the absence of a comparison with ethics committees in other countries restricts the applicability of the findings to other developing nations beyond the Indian context.[8]

Inherently, ethics committees often encounter various challenges during the preapproval stage of protocol review, which include ensuring the safety of vulnerable populations, conducting risk–benefit analyses, addressing issues related to informed consent, and facilitating posttrial access. Similarly, after approval, ethics committees face challenges related to the submission and reviewing of protocol deviations, reporting and reviewing serious adverse events (SAEs), conducting site monitoring visits (SMVs), providing updates on the study's progress, and submitting annual reports. In addition, the lack of institutional support, inadequate infrastructure, insufficient manpower, and limited access to necessary tools such as software and computers hinder the effective tracking of protocols before and after approval. The review process for postapproval submissions is further impeded by excessive paperwork and administrative burdens.[6,9]

To tackle these challenges and enhance postapproval oversight, the participating member secretaries put forward a range of solutions. These solutions encompassed various aspects, such as conducting regular training programs that specifically address postapproval activities, fostering greater awareness of standard operating procedures, and providing additional resources and personnel to ethics committees. In addition, they recommended the adoption of automated

digital platforms to facilitate the tracking and scheduling of oversight activities, while ensuring data protection measures are in place. These recommendations hold significant importance as RECs are primarily dedicated to upholding the rights, well-being, and safety of participants. Furthermore, maintaining data credibility is another crucial responsibility entrusted to the site members.[6,7]

Data fraud in studies is another pressing issue that undermines the integrity of research findings. RECs, investigators, and sponsors play a crucial role in addressing this challenge. By implementing robust postapproval oversight measures, RECs can scrutinize the data collection and analysis processes more effectively. This can include regular audits, data verification, and promoting transparency and accountability among researchers. Furthermore, fostering a culture of ethical conduct and providing education on research integrity can help prevent data fraud and promote responsible research practices.[10]

There is also a need to enhance the monitoring system within ethics committees to ensure the ongoing ethical compliance of approved research. The findings align with existing literature, which highlights the deficiencies in monitoring processes. Strengthening SMVs, improving the reporting of SAEs and protocol deviations, and increasing institutional support are the essential steps in this regard.[9] According to the 2019 ongoing review of the New Drugs and Clinical Trials Rule, it is recommended to conduct regular monitoring for reviewing clinical trials.[11]

The potential of accreditation and assessment programs in enhancing postapproval oversight has been recognized. To further strengthen this aspect, it is imperative to expand and ensure the widespread availability of these programs to ethics committees nationwide. While accreditation is currently a voluntary endeavor, it should be made mandatory, as exemplified in China, where nonaccredited committees are ineligible for national grants. The process of accreditation not only elevates the credibility of the committee but also establishes a framework for ongoing enhancement and adherence to best practices.[12]

Ethics committees should collaborate and have a dialog with regulatory authorities, research institutions, funding agencies, and other ethics committees to establish a standardized framework for postapproval monitoring. This framework should consist of unambiguous guidelines, standardized reporting formats, and the implementation of regular training programs for committee members. In addition, allocating financial resources for monitoring activities, including logistics and incentives, is crucial to ensure effective oversight. By incorporating these elements, the framework can provide a robust structure that supports the ethical conduct of research and ensures the well-being of participants. By aligning their efforts and sharing resources, stakeholders can collectively work toward strengthening postapproval oversight.

Investing in technology can significantly streamline the postapproval oversight process. Digital platforms can be developed to automate the tracking and scheduling of oversight activities, facilitate document submissions, and provide real-time monitoring of ongoing research. These platforms can also ensure data security and confidentiality, addressing concerns related to the handling of sensitive information.[13]

Taking a proactive stance toward addressing protocol deviations necessitates concerted efforts. Ethics committees should collaborate closely with principal investigators to establish comprehensive guidelines for reporting and managing protocol deviations. It is worth noting that research methodology training is mandatory for all faculty members, as per the National Medical Council guidelines.[14] However, considering that many investigators fail to adhere to research protocols, it becomes imperative to provide separate training specifically focused on reinforcing adherence to the research portfolio. Furthermore, conducting regular reviews of protocol deviations and imparting training to committee members on the assessment of protocol modifications are the essential steps to maintain consistency and ensure compliance with established protocols.[15]

Standardizing and closely monitoring the reporting and review process of SAEs is crucial. It is essential to educate principal investigators on the significance of promptly and accurately reporting SAEs. In addition, committee members should receive training in assessing and determining causality. To facilitate this, faculty from pharmacology departments or the pharmaceutical industry can be called to provide specialized training regarding SAE reporting. It is important to emphasize the need for complete independence in the reporting and review process. By fostering collaboration between ethics committees and regulatory authorities, a robust reporting system can be established, safeguarding the safety, and well-being of research participants effectively.[16]

Ethics committees should advocate for increased institutional support and allocation of resources for postapproval oversight. Adequate staffing, infrastructure, and financial resources are necessary to carry out

effective monitoring and review activities. Institutions and funding agencies should recognize the critical role of ethics committees in ensuring ethical research practices and provide the necessary support to fulfill their responsibilities.[6]

CONCLUSION

While preapproval review processes receive significant attention in research ethics, postapproval oversight is equally vital in ensuring the ethical conduct of research studies. Strengthening postapproval oversight requires addressing the challenges faced by ethics committees and implementing effective solutions. Collaboration between regulatory authorities, research institutions, and funding agencies, along with the adoption of technology and standardized frameworks, can greatly enhance the monitoring and review processes. By prioritizing postapproval oversight, we can uphold the principles of research ethics, protect the rights and well-being of research participants, data credibility, and foster trust in the scientific community.

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