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From guideline to practice: Active monitoring by research ethics committees in South Africa

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Post-approval monitoring is a cornerstone of research ethics oversight. Although securing initial ethics approval is a widely accepted prerequisite for research studies, systematic oversight after approval often remains neglected, particularly in resource-constrained settings such as South Africa (SA). This article reflects on the role, challenges and opportunities of post-approval monitoring by research ethics committees (RECs) in SA, drawing on national guidelines and emerging innovations. Effective post-approval active monitoring requires reframing REC oversight as a collaborative, educational partnership rather than a purely regulatory function. However, sustainable implementation remains limited by chronic underfunding and uneven institutional capacity. Community engagement holds promise in strengthening accountability, while participatory models, including community-based monitoring, are essential for building trust and ensuring local relevance. Digital innovations such as RHInnO Ethics and AI-based tools could serve as force multipliers if developed responsibly, aligned with local values, and under strong human governance. Strengthening post-approval active monitoring in SA necessitates a multipronged strategy. In this article we discuss four interlinked challenges: collaborative approaches between RECs and researchers, funding constraints, community engagement in oversight, and the use of digital technologies to augment monitoring capacity.

Keywords: active monitoring, post-approval monitoring, passive monitoring, research ethics committees, community engagement

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In the research ecosystem, obtaining an ethics approval before a study begins is a requirement for all research activities.[1] Post-approval monitoring is an ongoing oversight of research by research ethics committees (RECs) after a study has received initial ethical approval. Monitoring by RECs can occur through two complementary modalities: passive (paper-based) and active (on-site) monitoring. Maintaining a clear distinction between these approaches supports conceptual clarity, proportionate oversight, and transparent escalation pathways. Passive monitoring relies on document review, e.g. periodic progress and safety reports, adverse event summaries, and other submitted materials. Active monitoring entails a site visit and direct verification activities. Site visits are indicated for high-risk research, to investigate adverse events and serious adverse events.[2] However, active monitoring is often overlooked.[1] The reasons for this situation in practice are multifactorial, such as capacity, time pressure and funding. Although there is nothing we can do to address the time pressure issues, to develop any meaningful capacity requires funding to train and develop capacity for REC members. The majority of these REC members are academics who are already overburdened.

Effective post-approval monitoring is essential to ensure that researchers adhere to the approved protocol, that participant welfare remains protected, and that emerging ethical or safety issues are promptly addressed. Past scandals – from the Tuskegee syphilis study in the USA to South Africa (SA)'s own Bezwoda trial in 1995, where a chemotherapy study was conducted without consent or ethics review – highlight the grave consequences of research misconduct on vulnerable research participants.[3,4]

The 2024 update to the SA ethics in health research guidelines (3rd edition, section 5.5.1.12) reinforces a critical but often under-realised mandate: RECs must transition from being gatekeepers of protocol entry to active overseers of ongoing study conduct.[2] While the National Department of Health provides the regulatory scaffolding for active monitoring, translating these principles into robust oversight remains a significant challenge within the SA research ecosystem.

Strengthening post-approval monitoring in SA is therefore a pressing concern in research ethics. The perspective presented in this review reflects our experience with the key challenges and emerging opportunities for active monitoring by RECs in the SA context, focusing on four inter-related aspects: (*i*) collaborative approaches between RECs and researchers; (*ii*) funding constraints; (*iii*) community engagement in oversight; and (*iv*) the use of digital technologies to augment monitoring capacity. These domains offer insight into how SA RECs can bolster post-approval oversight in a manner that is ethical, practical, and aligned with global best practices.

Collaboration between RECs and researchers in monitoring

An effective post-approval monitoring system thrives on a collaborative rather than adversarial relationship between RECs and researchers. Traditionally, ethics committees might be seen as regulators and

principal investigators as the regulated. However, ensuring ongoing compliance and ethical conduct is a shared responsibility that benefits from open communication, mutual trust, and education. In practice, this means moving towards a model where monitoring visits are approached as collegial and educational exercises helping researchers meet ethical standards, instead of as 'inspections' seeking infractions. For example, the Northwestern University Institutional Review Board in the USA frames its post-approval monitoring visits as 'collaborative, education-focused reviews' aimed at improving study conduct.[5] The University of Texas at Dallas describes its post-approval monitoring programme as one that 'safeguards participant welfare, provides educational support to researchers, and identifies areas for improvement', with reviews often conducted proactively or at a researcher's request.[6] These approaches underscore the need for monitoring to serve as a form of quality improvement and support for researchers, not just compliance enforcement. Fostering research integrity is not the task for one office or person. Teamwork can embed integrity into research environments.

Active monitoring serves distinct but complementary roles in research ethics and integrity. Its ethical function is participant centred, ensuring ongoing protocol adherence, informed consent, and risk-benefit management to safeguard welfare. Its integrity function is science centred, promoting honesty and rigour by preventing data falsification, selective reporting, and protocol deviations to ensure methodological validity. Effective monitoring therefore operates at the essential intersection: protecting participants through ethical vigilance while ensuring credible results through integrity oversight.

RECs and investigators should view each other as partners working towards the common goal of ethical, high-quality research. Regular communication is key. RECs can establish clear channels for researchers to ask questions or flag issues that arise during the study, without fear of automatic study suspension or punishment. Likewise, researchers should promptly inform the REC of any protocol deviations, unanticipated problems or changes in risk, understanding that the committee's role is to help navigate these challenges in a way that protects participants. This partnership approach can prevent minor issues from snowballing into serious non-compliance. When researchers see RECs as supportive allies, they are more likely to be transparent and proactive in reporting, enabling a 'no surprises' environment where ethical issues are jointly managed rather than hidden.

One practical strategy for strengthening collaboration between researchers and RECs in SA is comprehensive, ongoing research integrity training, in addition to good clinical practice and ethics training, which should be extended to postgraduate students, academic supervisors and research staff. Although some RECs already offer guidance, evidence suggests that broader, structured training is still needed. Engelbrecht *et al.*[7] reported a surge in institutional requests for ethics training across the Southern African Development Community, including for postgraduate students and supervisors, as part of building shared capacity and norms. A survey of 92 attendees at a research ethics training course reported that the training improved critical thinking, problem-solving, and project design skills across research levels, including for graduate students.[8]

Training should encompass critical topics such as informed consent, adverse event reporting, protocol amendments, ongoing ethical responsibilities after approval, and the impact of digital technologies on the research ecosystem. Offering such training transforms RECs from being perceived merely as gatekeepers into collaborative partners that support ethical research conduction. Institutional leadership also plays a vital role. For instance, institutional supportive structures enable RECs to enforce compliance effectively, while minimising the risk of consequentialist mentality where researchers feel pressured to prioritise rapid results over responsible conduct of research. Collaboration is a linchpin for successful post-approval monitoring. By providing guidance, training, and a non-punitive avenue for addressing issues, RECs can cultivate researchers' 'buy-in' to ethical compliance. This guidance not only makes oversight more effective (since it is easier to monitor a co-operative investigator than an unco-operative one) but ultimately promotes a research culture in which ethics is integrated into everyday practice rather than being a mere administrative hurdle. This collaborative ethic should extend beyond the researcher-REC dyad to include meaningful partnerships with the communities hosting the research.

Community-based monitoring as a complementary practice

While the inclusion of a community representative on REC site visits is a vital step, a more robust model of community engagement in oversight involves structured community-based monitoring (CBM).[9-11] CBM is particularly critical in the SA context, where much research is conducted in rural communities bearing a heavy burden of disease, poverty and infrastructural neglect. In these settings, community members are not merely participants but key stakeholders who can act as a bridge to the research team, providing real-time, grounded feedback on the study's conduct and impact.

The co-operative relationship between RECs and community monitors can transform oversight. CBM offers several key benefits: it can build trust and overcome historical mistrust by ensuring that community voices are heard directly in the oversight process; provide contextual intelligence on issues such as the true comprehensibility of consent processes or the social impact of trial participation; and enhance accountability by creating an additional layer of transparent, localised scrutiny. This aligns with an *ubuntu*-informed approach to research ethics, where relational accountability and communal welfare are integral to ethical conduct.[12,13]

However, such co-operation also presents risks that must be proactively managed. These include the potential for conflicts of interest within small communities, the risk of burdening community members without adequate compensation and support, and the need to ensure that monitors are properly trained to understand their role without being co-opted by the research team. The relationship between research sites and their host communities must therefore be carefully nurtured, moving beyond a transactional dynamic to one of sustained partnership.

Researchers and RECs can design monitoring frameworks that leverage CBM by integrating it into existing structures. This process could involve establishing clear, safe channels (e.g. dedicated hotlines, community liaison officers) for direct feedback from participants and community monitors to both the research team and the REC, and co-developing monitoring tools with community advisors to assess locally relevant ethical concerns, such as fair participant selection, post-trial access, and the study's social footprint.[12,13]

Formally incorporating anonymised community feedback into the REC's periodic continuing review process provides a robust REC oversight. Integrating CBM does not replace REC authority, but enriches it. By creating a formal feedback loop between community monitors and the REC, oversight becomes a multidirectional dialogue. This approach helps ensure that monitoring is not only about verifying procedures on paper, but also about understanding the lived experience of research on the ground, leading to more ethical, respectful and impactful science.

REC engagement with researchers in research oversight

The effectiveness of active monitoring in research ethics oversight is contingent on structural capacity, resources of RECs, and sustained, constructive engagement with researchers. Such engagement requires deliberate time investment, as both RECs and investigators must appreciate that ethical oversight is an iterative process rather than a once-off review. Within our context, active monitoring mechanisms such as site visits, periodic progress reports and audits are important oversight strategies.[14-17] These approaches enable researchers to navigate emerging ethical challenges, including unanticipated risks or protocol deviations, while reinforcing competence in regulatory and ethical practices.[14-16,18] Furthermore, collaborative oversight can mitigate adversarial dynamics that discourage disclosure of difficulties, thereby reducing the likelihood of ethical lapses.

Operationalising this collaborative vision requires a clear allocation of responsibility across three interconnected levels.[17] Primary responsibility for systemic capacity-building rests with the host institution (e.g. the university or research organisation), which should provide the necessary resources and mandate structures such as a dedicated REC or research ethics and/or research integrity office. This office can co-ordinate structured training initiatives, including workshops on research ethics, courses on good clinical practice, adverse event reporting, and protocol amendment procedures. Responsibility for relational, context-specific mentorship during active monitoring is shared but differentiated: the REC as a whole sets ethical standards; designated REC members or designated monitors deliver day-to-day guidance during site visits, acting as educators rather than inspectors; and researchers share responsibility by engaging proactively with feedback as part of learning, not merely compliance. Without institutional resourcing, REC co-ordination and researcher engagement, these activities become an unsustainable burden on REC members.[17]

REC-researcher engagement, including the role of the community representative, should be conceptualised as an iterative process that strengthens ethical resilience within research systems. Operationalising it requires clear allocation of responsibility across three levels. The host institution bears primary responsibility for systemic capacity-building (e.g. training programmes).

REC-researcher engagement, as well as engagement with the community representative, should be conceptualised as an iterative process that strengthens ethical resilience within research systems. By embedding active monitoring in relationships of mutual respect and accountability, RECs can enhance participant protection, improve scientific quality, and advance a culture of ethics that extends beyond procedural compliance.

Funding as a challenge for active monitoring

One of the most significant barriers to effective active monitoring in SA is the chronic underfunding of RECs. Active monitoring activities such as site visits, data audits, training and database management demand sufficient financial support. A survey of SA health RECs observed that 'funding of RECs is a perpetual problem at most institutions as these bodies receive low priority within institutions'.[19]

To bridge the gap, many SA RECs levy review fees, typically charging a one-time fee for industry-sponsored or externally funded studies while waiving charges for unfunded academic projects. However, fee revenue is uneven and often modest, particularly at smaller or historically disadvantaged institutions with limited access to externally funded research.[19] All these fund-raising activities can still not sustain active monitoring processes, and as a result, active monitoring is frequently curtailed.

Site visits are essential for robust active monitoring activities, but remain rare because of their associated travel and personnel costs. Similar challenges are evident across other low- and middle-income countries; in Nigeria, for example, oversight after approval is documented to be 'poor' largely owing to inadequate resources, despite a growing number of committees.[20]

Recent African guidance highlights the severity of this constraint: 'RECs need basic funding for administration, equipment, communication ... and more than basic funding for oversight activities, training, digital platforms, etc. As research becomes more complex ... RECs require more financial resources. And that is where Africa experiences a serious bottleneck.'[20] Adequate funding is therefore not only critical to the independence and efficient operation of RECs, but also indispensable for keeping pace with increasingly complex multicentre trials and public health emergencies.[21] Addressing funding issues would help with strengthening active monitoring, and without sustainable financial support, even well-intentioned recommendations such as adopting digital platforms and expanding training would fail.

Ethics oversight is beginning to be recognised as a core component of professional research infrastructure in Africa, and some institutions have secured stronger support as they appreciate the reputational and scientific value of robust ethics governance. Stakeholders, including university leadership, the National Department of Health and international partners, must confront the reality that adequate, transparent and sustainable financing is not a luxury but a necessity. Financial support in REC functions such as active monitoring is ultimately an investment in preventing ethical lapses, safeguarding participants, and sustaining public trust in the research enterprise.[21]

Digital innovation and artificial intelligence for strengthening post-approval monitoring in SA

Technological innovation, particularly artificial intelligence (AI), offers significant potential to augment post-approval ethics oversight in resource-limited contexts such as SA. Integrating AI into established platforms such as RHInnO Ethics can automate routine administrative tasks, analyse large data sets for anomalies, and streamline the review of complex reports through natural language processing.[22] These tools could enable RECs to monitor compliance, track study progress,

and flag protocol deviations more efficiently, addressing chronic challenges of understaffing and high workloads.[23]

However, deploying AI requires cautious governance. Models must be carefully managed to mitigate algorithmic bias and ensure that they serve as decision-support tools rather than replacements for human judgement. Implementation also demands technical infrastructure, data governance protocols and training resources that remain limited in many settings. Ultimately, when ethically guided by frameworks such as *ubuntu* and maintained under meaningful human supervision, AI can act as a force multiplier, enhancing both the efficiency and integrity of research oversight.[24,25]

Conclusion

Post-approval monitoring remains a critical yet underdeveloped element of research ethics governance in SA. Policy frameworks mandate oversight beyond initial approval, and the translation of these mandates into consistent practice is hindered by financial, infrastructural and human resource constraints. Current evidence indicates that post-approval monitoring is most impactful when framed as a collegial, capacity-building partnership between RECs and researchers. However, key gaps remain that warrant systematic scholarly enquiry.

Future research should investigate several pressing questions. First, what models of sustainable financing can be developed to support active monitoring across diverse SA institutions, including historically under-resourced universities? Second, how do collaborative approaches between RECs and investigators, particularly those grounded in mentorship and educational engagement, affect compliance, researcher integrity, and participant protection? Third, how can structured CBM models be sustainably implemented and effectively integrated with REC oversight to provide actionable, real-time feedback while protecting community monitors? By addressing these questions, post-approval monitoring moves from a compliance-orientated afterthought to an evidence-informed, ethically resilient practice that both protects participants and sustains public trust in SA research.

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