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Guest editorial: medical research ethics review in China – key developments and continuing challenges, with insights from our experience in Shenzhen

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China's biomedical research sector has been expanding at an extraordinary pace, driven in part by national investments in artificial intelligence (AI), genomics and synthetic biology.[1] These advances hold considerable promise for societal benefit, but they also raise new risks and uncertainties for individuals and communities. Moreover, research itself—particularly when human participants are involved—can generate risks that demand careful ethical oversight. Ethics review, a central mechanism for protecting research participants, is therefore essential for identifying and reducing possible harm. The key challenge now facing China's policymakers, researchers and ethicists is to develop an adaptive, modernised governance framework: one that safeguards participants while supporting responsible innovation and maintaining public trust.

In this guest editorial, we draw on our experience in Shenzhen—a city at the forefront of China's biomedical and technological innovation—to illustrate China's developing ethics review practices. We also draw attention to continuing gaps in coordination, capacity building and risk governance and suggest that Shenzhen's approach to addressing these issues, though still a work in progress, can inform policymakers in other cities.

We begin by describing the historical context that shaped China's current ethics review system, along with recent policy and legal reforms.

FROM FRAGMENTED OVERSIGHT TO COORDINATED GOVERNANCE

For most of the 1990s and early 2000s, China's ethics review of biomedical research developed unevenly across different domains, including animal experimentation, life sciences research and clinical trials. Early protections for human subjects were introduced through international collaboration. Ethics committees (ECs) were often under-resourced and lacked relevant training and experience.[2 3]

As China's life-sciences industries expanded, the country saw rapid breakthroughs in areas such as gene editing, reproductive technology and brain–computer interfaces. Some advances, however, were accompanied by major controversies—most notably the 2018 'CRISPR(Clustered Regularly Interspaced Short Palindromic Repeats) babies' case. He Jiankui, a Chinese biophysicist, announced the birth of twin girls whose genomes he and his team had edited using CRISPR technology, introducing heritable (germline) changes.[4] The announcement sparked outcry amid concerns about inadequate regulatory oversight, prompting calls for reform both in China and internationally.[5]

The Chinese government's response has been sweeping. It has included the introduction and tightening of national regulations on human genetic resources and biomedical research, criminal penalties for unauthorised clinical genome editing, steps towards greater central coordination across ministries, and the elevation of ethics review as a mandatory, front-end requirement for life-sciences research involving humans.[6]

The *Measures for the Administration of Science and Technology Ethics Review*, published in 2023 and jointly issued by 10 government agencies, represents the country's first attempt at an integrated, top–down approach to ethics governance of emerging science and technologies, in which the life sciences, medicine

and AI are highlighted as key areas.[7] The report took a problem-oriented approach, focusing on resolving issues such as unclear responsibilities, irregular procedures and incomplete mechanisms for scientific ethics review by conducting in-depth surveys to formulate the policy. The scope of ethics review for life science and medical research involving human participant has been expanded from medical institutions to include institutions of higher education, research institutes and other entities.

At the national level, the regulatory responsibilities for biomedical research involving human subjects have been divided as follows: the National Health Commission for medical institutions; the National Administration of Traditional Chinese Medicine for traditional Chinese medicine research; and the Ministry of Education for medical universities.[8 9] The National Medical Products Administration focuses on clinical trials specifically for the registration of new drugs and medical devices.

Regional ECs (RECs) have also been established in cities such as Beijing, Shanghai and Shenzhen. Their purpose is to help address capacity gaps by providing review services, training and supervision for research activities conducted at specific institutions.[10] At the same time, RECs themselves vary in experience, expertise and how clearly their scope and mission are understood. The gradual introduction of national registration and planned accreditation for ECs should help promote greater consistency across RECs, while also clarifying roles and responsibilities.[8 9]

PERSISTENT TENSIONS

Despite the rapid, recent reforms described above, important challenges remain with current medical research evolving towards greater integration of data, AI and biotechnology—all characterised by increasing complexity, diversity and interdisciplinary trends. One persistent difficulty amidst these changes is striking the right balance between preventing harm and enabling responsible research.[11] As a corrective to prior inadequate regulation, China's current governance approach places strong emphasis on risk prevention and avoidance of triggering regulatory blowback. While due precaution is necessary, its overemphasis can encourage overly timid decision-making, particularly where rules are still evolving and underlying ethical principles are also debated.

Moreover, cutting-edge medical technologies not only impact participants but may also exert far-reaching effects on the interests of future generations and collectives. Faced with these complex value choices and ethical challenges, ECs need to assume greater responsibilities. In such contexts, researchers and ECs may default to procedural rigidity—delaying or discouraging well-justified studies because perceived regulatory complexity looms too large. Over time, this risks turning ethics review into a largely administrative exercise rather than a forum for proportionate, context-sensitive ethical judgement.

One way forward would be a more clearly risk-proportionate review framework, akin to those used in the USA and the UK among other jurisdictions, with exempt, expedited and full committee review pathways, alongside additional safeguards or specialist review for particularly high-risk research. At the same time, there are valid concerns about adopting externally developed frameworks 'off the shelf'—that is, without careful adaptation to, or translation across, potential cultural differences in local values and priorities.[12 13]

A second challenge concerns uneven capacity.[14] Ethics review in China remains most robust in major hospitals and elite universities. By contrast, the quality of ethics review in non-medical institutions or lower-tier universities remains a concern due to limited awareness of research ethics, shortages of trained personnel and insufficiently tailored operational guidelines and procedures.

A third issue is coordination. Multicentre clinical trials have long suffered from redundant reviews, inconsistent judgments and procedural inefficiencies. Efforts to promote 'collaborative review and mutual recognition'[15] of ethics approvals are under way, but full implementation remains nascent. Coordination challenges are further intensified by the rapid expansion in the scope of ethics review. Whereas ethics oversight was once largely confined to hospitals and medical universities, it now extends to a much wider range of actors, including research institutes and industry. This expansion brings together institutions with different mandates, capacities and regulatory cultures, increasing the risk of overlapping reviews, inconsistent standards and uncertainty about which body has decision-making authority.

Yet even as approaches to ethics review develop, deeper ethical concerns remain. Given the increasing complexity, uncertainty, interdisciplinarity and diversity of health research, how can ECs evaluate studies that cross traditional disciplinary or jurisdictional boundaries? For example, AI models trained on health data or synthetic biology projects with global implications pose challenges for more traditional approaches to ethics review. How can ethical governance keep pace with technologies whose social risks remain poorly understood? These questions are not just theoretical. They are already being confronted in cities at the vanguard of biomedical and technological innovation, such as Shenzhen.

THE SHENZHEN EXPLORATION AND EXPERIENCES

Shenzhen, as a hub for biotechnology, AI and brain science, has long been associated with the promotion of medical innovation. It faces both the promise and the risks and uncertainty of frontier research. The establishment of the Shenzhen Biomedical Ethics Committee (SBEC), compared with other regional ethics review approaches in China, stemmed from a practical bottleneck. Founded in 2017, SBEC was tasked with providing ethics review, consultation and training across institutions. It is a demand-driven, government-led initiative

Table 1 Benefits and trade-offs of regional versus institution-specific ECs

	Benefits	Trade-offs/limitations
RECs	► Capacity support: RECs can provide ethics review for institutions that lack the expertise, scale or resources to sustain a competent local committee. ► Pooled expertise: by serving multiple institutions, RECs can concentrate specialised knowledge (eg, in genomics, AI or cell therapy) that may be unavailable locally. ► Independence: greater distance from host institutions may reduce conflicts of interest and perceived pressure to approve institutionally valuable research. ► Consistency: RECs may promote more uniform standards and interpretations across institutions, particularly for multicentre or high-risk studies. ► Efficiency in some contexts: centralised review can reduce duplication where many institutions would otherwise review similar protocols independently.	► Lack of knowing local researchers: RECs may be less familiar with researcher background, qualifications and experiences. ► Weaker ongoing oversight: distance can make it harder to provide iterative guidance, monitor compliance or respond quickly to protocol deviations. ► Risk of bureaucratisation: centralisation may introduce additional procedural layers if roles and responsibilities are not clearly defined. ► Ambiguity of accountability: shared review authority can blur responsibility between institutions and regional bodies when ethical issues occur.
IECs	► Contextual knowledge: IECs are often better positioned to understand local research environments, investigators and participant communities. ► Responsiveness: proximity can facilitate dialogue with researchers and faster resolution of minor ethical issues. ► Clear accountability: responsibility for ethical oversight is more clearly anchored within the institution conducting the research.	► Capacity constraints: smaller or less resourced institutions may struggle to recruit trained members or maintain review quality. ► Inconsistency: decentralised review can lead to variable standards and decisions across institutions. ► Conflicts of interest: close institutional ties may increase real or perceived pressure to approve strategically important research.

RECs and IECs each offer distinct advantages, as well as important limitations. Which model is preferable depends on institutional capacity, research volume and the types of studies under review. Alternatively, in some cases, hybrid models—combining strong institutional responsibility with regional support, coordination or specialist review—may offer a more balanced approach than either model alone.
AI, artificial intelligence; ECs, ethics committees; IECs, institution-specific ethics committees; RECs, regional ethics committees.

supported by an annual dedicated fund of ¥3 million and entrusted to redacted for peer review for long-term institutional support.

Under the guidance of the Shenzhen Municipal Health Commission and redacted for peer review, we became engaged in ethics review policy development and capacity building, with one of us (redacted for peer review) appointed as a core member of the committee. SBEC now coordinates ethical oversight for local hospitals, universities and biotechnology firms, offering a regional support structure that complements national policy. The establishment of regional ECs can help relieve the burden on individual institutions—particularly those without the capacity to sustain their own committees—and may offer efficiency gains compared with fully decentralised review alone (see table 1 for discussion and caveats).

The Shenzhen approach—anchored in municipal leadership but guided by national standards—has so far proved promising not only because it has expanded ethics-related activities, but because it has begun to change how ethics review is coordinated and supported in practice. Through SBEC's work, the city has progressively developed an integrated ethics review support and oversight system operating at both project-based and regional levels. This has helped reduce fragmentation across institutions by clarifying review responsibilities, standardising expectations and creating more consistent channels of communication between ECs and regulators.

In addition to routine inspections, training programmes and academic exchanges, SBEC's work has informed the establishment of a dedicated Science and Technology Ethics Service Center under the guidance of the Shenzhen Municipal Bureau of Science, Technology and Innovation.[i] This centre is intended to function as a standing interface between local authorities and research institutions, enabling earlier consultation, faster escalation of complex cases and more coordinated responses to ethically sensitive research. Together, these measures aim to make ethics review not only more rigorous, but also more predictable and efficient, supporting timely and well-justified decision-making rather than ad hoc or purely procedural review. It will play a vital role in building a modern science and technology ethics governance ecosystem.

Even so, important challenges remain around the diffusion of responsibility.[3] Under current policies,

[i] [1]Shenzhen Municipal People's Government General Office Issues Implementation Plan for Strengthening Scientific and Technological Ethics Governance. Shenzhen Government Online. https://www.sz.gov.cn/szzt2010/zdlyzl/kjcy/yhzc/content/post_11969436.html (accessed 3 January 2026).

research institutions are formally designated as the primary responsible entities and are expected to bear full accountability for their research projects. In practice, however, many institutions rely on RECs to conduct reviews or ethics checks, while oversight has increasingly been distributed across multiple levels. In particular, a three-tier ethics review structure has emerged, involving institutional, provincial or municipal, and national committees. For conducting certain high-risk research on emerging technologies, an expert review process should be organised by the local government after the preliminary ethical review is conducted by the research institution. According to the Regulations on the Administration of Clinical Research and Clinical Translation and Application of New Biomedical Technologies issued by the State Council in 2025 and taking effect on 1 May 2026, cell therapy clinical research can be launched without waiting for approval from national or provincial authorities. Only completing the 'filing' with the National Health Commission is required after the institution completes the 'science review' and 'ethical review'. The National Health Commission will conduct dynamic evaluations.

While this layered system is intended to strengthen protection, it can also blur lines of responsibility. When ethical approval is distributed across multiple committees, institutional liability alone may no longer capture who is ultimately responsible for protecting research participants and ensuring ethical integrity. This raises a practical governance question: When risks materialise or ethical failures occur, where does responsibility ultimately lie?

WHAT NEEDS TO BE DONE

China's reforms represent a significant evolution—from patchy or non-existent ethics review, to compliance-driven oversight, to a more reflective and risk-aware system—but the work is far from complete. Based on our experience with SBEC in Shenzhen, and on discussions with ethics leads in other Chinese cities and regions, three priorities for the future stand out.[ii]

First, capacity-building must continue at both individual and institutional levels. Ethics review requires not only procedures but people with the expertise to interpret and apply them. Systematic education in research ethics should be embedded in graduate training and professional development across all sectors involved in human-participant research.

Second, interdisciplinary collaboration is crucial. The ethical challenges of modern science—from genetic editing to AI-mediated decision-making—cannot be addressed by any one field alone. China's emerging network of ECs and expert databases should be used to foster dialogue among scientists, ethicists, sociologists, legal scholars and the public.[16] Greater empirical and conceptual work by ethicists is needed to support applied ethical decision-making. Ethics serves as a bridge for dialogue between the public and science, enhancing public trust. This all requires systematic design and close coordination, or even integration, among relevant parties.

Third, balance and proportionality must guide the next stage of reform. Oversight should protect participants without paralysing innovation. Procedural rigour should not eclipse moral reasoning. Policymakers should cultivate an ethical culture in which responsibility is shared and guidelines are co-developed through reasoned discussion, not merely enforced. In addition, the ethical governance of emerging cutting-edge technologies cannot rely solely on ethical reviews; it necessitates a full-cycle process of dynamic assessment and regulatory supervision.

LOOKING AHEAD

China's system of ethics review has moved rapidly from fragmented oversight towards more coordinated, nationally and internationally informed governance. This shift reflects a growing recognition in China that science and ethics are mutually reinforcing. Shenzhen's experience shows that local innovation, when coupled with national vision, can produce meaningful reform. Still, the long-term success of China's recent prioritisation of biomedical research ethics review will depend on whether ethical deliberation becomes a routine and respected part of scientific life.

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[ii] [2]These challenges are not unique to China. Similar capacity-building priorities arise across many countries in the Global South, and strengthening ethics governance remains an ongoing task in the Global North as well.[12 13]

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