Towards Multi-Dimensional Collaborative Governance of Medical Research Integrity in China: A Stakeholder-Centric Strategy

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***Abstract*—Medical research integrity, fundamental to scientific advancement and public trust, confronts acute challenges posed by pervasive misconduct in China. Employing stakeholder theory, this study undertakes a qualitative synthesis to scrutinize the complex interplay of interests and strategic interactions among key actors—researchers, institutions, funders, publishers, and regulatory bodies—within the governance of research integrity, thereby uncovering inherent systemic deficiencies. We subsequently propose a multi-dimensional collaborative governance framework with role differentiation. This framework articulates distinct responsibilities for each stakeholder, designed to foster inter-stakeholder synergy and enforce mutual accountability. It aims to bolster the authenticity and credibility of research outcomes, optimize resource allocation, and ensure the sustainable advancement of medical research in China. The study offers critical theoretical insights and pragmatic strategies for enhancing the efficacy of China's medical research integrity governance system.**

Keywords-medical research; scientific research integrity; stakeholders; collaborative governance; multiple subjects.

I. INTRODUCTION

In recent years, with the rapid development of China's science and technology sector, significant achievements have been made in medical research. However, issues of research integrity have also become increasingly prominent. Research integrity is the cornerstone of scientific innovation and a critical factor in ensuring the healthy development of research activities. Yet, problems, such as data fabrication, plagiarism, and ghostwriting are all too common, severely impacting the international reputation of China's medical research and the healthy development of its research ecosystem. To address these issues, the state and relevant departments have successively issued a series of policy documents aimed at strengthening research integrity, standardizing research practices, and improving research quality. First, the national level places great emphasis on the construction of research integrity. In 2018, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council issued the "Several Opinions on Further Strengthening Research Integrity Construction," which clearly states the need to establish and improve a research integrity management system, strengthen research integrity education, and strictly investigate acts of research dishonesty. Given the special nature of medical research, relevant departments have also formulated specific policy documents [1]. In 2021, the National Health Commission, the Ministry of Science and Technology, and the National Administration of Traditional Chinese Medicine released the "Code of Conduct for Medical Research Integrity and Related Behaviors," which outlines the integrity requirements for medical researchers in areas, such as study design, data collection, and paper publication [2]. The implementation of these policies has provided strong institutional support for the construction of medical research integrity. While China has established a robust policy framework, the actual effectiveness and uniformity of implementation at the grassroots level still require further critical evaluation and optimization.

The development of medical research not only relies on support from funding, technology, and talent but also requires the improvement of a scientific integrity management system and the coordination of multiple stakeholders to optimize resource allocation, enhance the authenticity of results, and boost public trust. In the context of deepening reforms in the science and technology system, establishing a comprehensive management mechanism and a robust scientific integrity system has become a crucial issue for promoting high-quality development in medical science and technology. This study aims to analyze the multi-stakeholder dynamic in medical research integrity management based on stakeholder theory, and to construct a collaborative management approach to ensure the credibility and sustainable development of medical research in China. Stakeholder theory is particularly suitable for this analysis due to its focus on the diverse interests and influences of various groups, which often conflict. While institutional theory might focus more on formal rules and principal-agent models on contractual relationships, stakeholder theory provides a broader lens to understand the complex web of interactions and power dynamics.

The remainder of the paper is organized as follows: In Section II, we discuss the background and significance of research integrity in medical research. Section III presents the methodology used in this study. In Section IV, we analyze the multi-stakeholder game dynamics and propose a collaborative management approach. Finally, Section V concludes the paper and provides future research directions.

II. Theoretical Basis

A. Definition of medical research integrity

Medical research integrity is the core ethical principle in medical research activities, encompassing the authenticity, objectivity, and ethical compliance of research practices. The *Code of Ethics for Medical Research Integrity and Related Conduct* defines medical research behavior as involving all aspects of the process from project application, implementation, data reporting, publication of results, to evaluation and acceptance, across fields, such as basic medicine, clinical medicine, preventive medicine, pharmacy, and traditional Chinese medicine. The U.S. Federal Policy on Research Misconduct, enacted in 2000, defines "research misconduct" as: fabrication, falsification, or plagiarism in project planning, performance, or project review, or in the reporting of research results [3]. These unethical behaviors not only undermine the credibility of research outcomes but can also pose direct threats to patient health and public safety [4]. For example, the 2018 "heart stem cell research fraud incident," which led to data fabrication causing a halt in the field's research, highlighted the profound negative impact of integrity issues on medical progress. In recent years, the use of generative artificial intelligence in paper writing has become a new challenge to integrity. At the same time, the unique nature of the medical field further complicates research integrity: Firstly, the current research evaluation system's excessive reliance on the number of papers and impact factors (i.e., the "SCI supremacy" orientation) [4] can easily lead researchers to prioritize short-term results over rigor; Secondly, medical research directly involves human life and health, requiring strict adherence to ethical review and participant protection principles (such as informed consent and privacy confidentiality). However, the lack of transparency in experimental data and the difficulty in verifying reproducibility make it hard to promptly identify errors or biases [5]. Therefore, medical research integrity is not only an issue of academic standards but also an ethical responsibility concerning social trust and public health.

B. Stakeholder theory

Stakeholder Theory originated in the field of business management in the 1960s, emphasizing that organizational decisions must balance the demands and impacts of multiple stakeholders. This theory was later introduced into public health management and research integrity, becoming a systematic tool for analyzing complex social issues [6]. Globally, stakeholder theory has been applied to biomedical governance to understand and manage conflicts of interest, ethical concerns, and resource allocation in research. In medical research integrity management, the stakeholder analysis framework includes the following steps: identifying stakeholders, which involves defining individuals or groups directly or indirectly affected by research activities, such as researchers, research institutions, funders, journal publishers, regulatory bodies, and the public; analyzing influence and interests, assessing the power levels, interest claims, and potential conflicts of each party in research activities, for example, funders may influence the objectivity of research conclusions through funding [7]; categorizing management strategies, dividing stakeholders into supportive, marginal, mixed, or non-supportive based on their cooperation and threat levels, to develop differentiated coordination mechanisms; formulating participation strategies, promoting multi-party collaboration through institutional design, such as establishing joint regulatory committees or open science platforms, balancing academic freedom with social responsibility [8].

III. Research Status

In recent years, China has significantly improved its policy and legal framework for managing medical research integrity. The introduction of multiple regulations and guiding documents reflects the country's high regard for research ethics. In 2021, the National Health Commission, in conjunction with the Ministry of Science and Technology and the National Administration of Traditional Chinese Medicine, revised and released the *Code of Ethics and Related Conduct in Medical Research*, which outlines ethical requirements throughout the entire process of medical research, including project application, research implementation, data management, and publication of results. It downplays the role of paper quantity and impact factors in evaluations while emphasizing integrity education and professional training [2]. In the same year, the General Office of the State Council issued the *Guidance on Improving the Evaluation Mechanism for Scientific and Technological Achievements*, further proposing to establish a robust system for managing research integrity and improve the reward and punishment mechanism linking achievement evaluation to integrity, aiming to curb academic misconduct at its source [9]. Additionally, the *Several Opinions on Further Strengthening Research Integrity Construction* issued by the Central Committee of the Communist Party of China and the General Office of the State Council in 2018 provided top-level design for medical research integrity, requiring the establishment of research integrity files, the implementation of lifelong accountability, and clear joint disciplinary measures for research misconduct [1]. The *Handbook of Research Integrity Standards* released by the Ministry of Science and Technology in 2023 further detailed the behavioral guidelines for researchers, reviewers, and management institutions, covering aspects such as topic selection, project application, and data usage, providing practical guidance for managing research integrity [10]. The intensive introduction of these policies shows that China is building a medical research integrity management system through multi-level and multi-dimensional institutional design.

However, despite these comprehensive policy initiatives, critical analysis suggests that challenges persist in the effective implementation and enforcement of these regulations. There may be gaps between the aspirational policy goals and the realities of practice at the institutional and individual researcher levels. Factors, such as insufficient resources for oversight, varying interpretations of guidelines, and entrenched academic culture focused on output metrics, could impede full

compliance. Furthermore, the absence of publicly available empirical validation or comprehensive impact assessments of these policies limits the strength of conclusions regarding their overall effectiveness, highlighting a need for more data-driven evaluation.

The systematic exploration of medical research integrity management by the international community began at the end of the 20th century. Developed countries, represented by the United States and the European Union, established relatively comprehensive governance frameworks through policies, regulations, and institutional development. The National Institutes of Health (NIH) in the U.S. was the first to propose *Responsible Research Practices* in 1989 and further introduced the Data Management and Sharing Policy in 2020, which clearly outlines data management, conflict of interest disclosure, and procedures for investigating misconduct. Its Office of Research Integrity (ORI) significantly enhances the credibility of biomedical research through independent oversight and educational training mechanisms, mandating that researchers publicly disclose raw data and analytical methods, and reinforcing the reproducibility of research findings [11]. The EU promotes cross-border collaboration through standardized policies; the revised European Code of Conduct for Research Integrity in 2023 provides uniform ethical review standards for member states and emphasizes the role of open science (Open Science) in enhancing transparency, such as requiring clinical trial data to be registered on public platforms and made accessible [12]. Australia, through its Responsible Research Conduct Code published in 2018, clarifies the responsibilities of research institutions, requiring them to develop internal policies to address misconduct and stipulating that compliance with these norms is a prerequisite for securing funding from the National Health and Medical Research Commission (NHMRC) [13]. These policies and regulations not only regulate research behavior through legal and institutional constraints but also focus on enhancing researchers' integrity awareness through education and cultural development. However, with the deepening of international cooperation, the coordinated governance of transnational research misconduct still faces challenges of legal application and jurisdictional conflicts.

IV. Management Challenges from the Perspective of Stakeholders

A. Classification and role of stakeholders

Medical research integrity management involves multiple stakeholders, whose roles are complex and multidimensional. The roles and functions of these stakeholders vary significantly based on their depth of involvement and influence. According to their functional positioning in research activities, they can be categorized into core stakeholders, secondary stakeholders, and external stakeholders.

Core stakeholders include researchers, research institutions, and ethics committees. Researchers, as the direct executors of scientific activities, have professional ethics and data authenticity as the foundation of integrity management. However, under the evaluation orientation of "SCI supremacy," researchers may overlook research rigor, leading to data fabrication or plagiarism [4]. Research institutions bear the responsibility for institutional design and internal supervision, and must establish an integrity management system through formulating ethical guidelines, improving review mechanisms, and establishing reward and punishment systems. Ethics committees, as independent supervisory bodies, must ensure that research complies with ethical standards, especially in clinical trials involving human subjects, where strict scrutiny of informed consent procedures and privacy protection measures is crucial [14]. In China, ethics committees play a critical role similar to IRBs in the US, ensuring that human subject research is conducted ethically and responsibly.

Secondary stakeholders include funders and publishing institutions. Funders influence research direction through funding allocation, but their potential intervention in research outcomes can lead to conflicts of interest, such as selective data disclosure required by commercial interests for corporate-funded clinical trials [7]. Publishing institutions, as the core channels for disseminating scientific research, must maintain academic credibility through rigorous peer review and data transparency requirements. However, some journals may lower their standards for reviewing high-risk studies to boost impact [15].

External stakeholders include policymakers and the public and media. Policymakers establish institutional frameworks through laws and regulations, but insufficient cross-departmental collaboration can lead to regulatory fragmentation. The public and media promote research transparency through public opinion pressure, yet their excessive focus on "breakthrough results" may exacerbate a short-sighted research orientation [16]. Ambiguous boundaries of authority and lack of coordination mechanisms result in regulatory blind spots, such as formalistic ethical reviews and lagging cross-departmental data sharing, highlighting the urgency of categorized management and collaborative governance [14][17].

B. Stakeholder interest demands and interplay

In the management of medical research integrity, games usually occur among different stakeholders. These games are originated from the differences in roles, responsibilities and interests of all parties in scientific research activities. By analyzing these game relationships, we can better understand the contradictions in the management of scientific research integrity and put forward coordination strategies. Building trust in these interactions is crucial; it involves transparent communication, adherence to agreed-upon norms, and consistent demonstration of ethical conduct by all parties, whereas breaches of trust can severely erode collaboration and legitimacy.

1) The game between researchers and researchers: The game among researchers focuses on the distribution of academic contributions, authorship rights, and the use of research resources. In team studies, the attribution of the first author and corresponding author often becomes a point of contention. Some core contributors may feel they have not received their due recognition, leading to internal divisions within the team

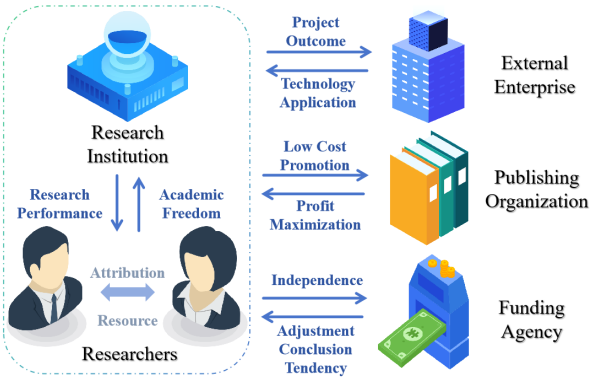

Figure 1. Game of stakeholders in "medical research integrity."

and even hindering research progress [4]. From a game theory perspective, this authorship conflict can be seen as a "zero-sum game," where one party's gain in terms of author order may mean a loss for the other.

2) The game between researchers and research institutions: The game between researchers and research institutions is also very significant. For example, researchers hope to maintain academic freedom and research independence, while research institutions focus more on overall research performance and the efficiency of resource allocation. Research institutions evaluate researchers based on the number of papers or funding indicators. This performance-oriented approach may lead researchers to prioritize short-term results at the expense of research integrity, such as data fabrication or exaggeration of research findings.

3) The game between researchers and funding agencies: Similarly, there is a game between researchers and funding agencies. Corporate or commercial sponsors may exert financial pressure, demanding that researchers selectively disclose data or adjust their conclusions to favor certain outcomes. For instance, if the results of clinical trials funded by pharmaceutical companies fall short of expectations, they might demand the concealment of negative data to protect business interests. Studies show that the policy orientation of funding agencies directly influences the design and implementation of research projects. For example, the National Natural Science Foundation constrains research misconduct through a reputation supervision mechanism, indirectly shaping the strategic choices of researchers. The optimization of this game relationship depends on communication and compromise in rule-making [18].

4) The game between scientific research institutions and publishing institutions: The game between research institutions and publishing houses is also reflected in the conflict between economic interests and scientific integrity. Research institutions strive to promote the widespread dissemination of their findings to enhance academic influence and social benefits, often preferring to place these results in the public domain or share them through low-cost channels. In contrast, publishing houses pursue maximum profit through strict copyright control and high subscription fees, treating academic achievements as tradable commodities. This difference in objectives leads to ongoing negotiations between the two parties on publishing models, fee structures, and accessibility of outcomes [19]. For example, the University of California engaged in a two-year negotiation with the publishing giant Elsevier over an open access agreement, which ultimately broke down due to conflicting interests [20].

5) Multi-party game: In the ecosystem of scientific research, complex interactions often occur among multiple parties including researchers, research institutions, funding agencies, and external partner companies. In cross-institutional research projects, researchers strive for personal academic achievements, research institutions focus on the overall impact of project outcomes, funding agencies emphasize the efficiency of fund utilization, while partner companies may prioritize economic returns from technology application. This multi-party dynamic relationship requires all parties to negotiate and compromise to form a balanced strategy, thereby maximizing overall benefits [16].

V. Conclusion

A. Government: Policy guidance and institutional guarantee

The government holds a central position in the top-level design and institutional supply of medical research integrity management. Through the formulation and enforcement of policies and regulations, it systematically standardizes research behavior and coordinates the responsibility boundaries of multiple stakeholders. In recent years, China has issued the "Several Opinions on Further Strengthening Research Integrity Construction" [1] and the "Code of Conduct for Medical Research Integrity and Related Behaviors" [2], establishing a system framework that includes penalties for dishonesty, data supervision, and ethical review. Specific measures include improving the legal system, establishing a tiered and categorized research integrity archive system, linking research misconduct to the social credit system, and strengthening joint punishment mechanisms, such as lifelong accountability for those responsible for data fabrication and plagiarism, and restrictions on their participation in project applications and evaluations; cross-departmental collaborative governance, integrating regulatory functions from the Ministry of Science and Technology, the National Health Commission, and the Ministry of Education, promoting data sharing and joint law enforcement to avoid fragmented regulation [17], while encouraging third-party independent institutions to participate in project assessments to enhance the objectivity of supervision [4]; reform of evaluation mechanisms, abandoning the "paper-only" orientation, and establishing evaluation standards centered on innovation quality, social value, and reproducibility, such as adding data traceability and repeated experimental validation steps in project acceptance to ensure the authenticity of results [7]; international cooperation and benchmarking, drawing on the research integrity policy framework of the National Institutes of Health (NIH) [11] and the EU's "European Code of Conduct for Research Integrity" [12], to improve the international standards of China's research integrity governance and enhance global academic discourse power.

B. Publishing institutions: Academic gatekeeping and transparency practices

Publishing institutions, as the core carriers of scientific research dissemination, need to maintain credibility through rigorous academic review and open science practices. This includes strengthening peer review mechanisms, implementing double-blind reviews, data transparency reviews, and dynamic peer evaluations to minimize conflicts of interest that could interfere with the fairness of the review process [15]. For example, requiring authors to submit raw data, experimental codes, and ethical review documents for experts to verify the reproducibility of their research; establishing early warning and correction systems to implement tiered alerts for journals with high rates of rejections or papers suspected of academic misconduct, and improving accountability mechanisms after rejections, promoting "post-publication peer review" (Post-Publication Peer Review), and encouraging continuous monitoring and revision of published results within the academic community [21]; advancing open science by supporting the widespread use of open access (Open Access), preprint platforms, and public databases (such as ClinicalTrials.gov), mandating the registration and publication of clinical trial data to avoid selective reporting risks; and standardizing AIGC usage by clearly defining the boundaries of AI-generated content in scientific writing, requiring authors to disclose the scope and specific functions of AIGC tools, and prohibiting their use to generate research conclusions, manipulate data, or fabricate experimental results [22].

C. Scientific research institutions: Internal governance and cultural ecology construction

Research institutions are the primary responsible entities for managing research integrity, and they need to build a sustainable integrity ecosystem through institutional constraints and ethical culture cultivation. Specific approaches include establishing an institutional management system, formulating detailed norms for research behavior, clarifying procedures for data management, authorship rights allocation, and conflict of interest disclosure, such as requiring researchers to sign integrity commitment letters during project initiation and regularly submitting original records of research progress; strengthening the ethics review mechanism, enhancing the independence and professionalism of ethics committees, involving external experts in high-risk research ethics reviews, and establishing a public disclosure mechanism for review results to prevent administrative interference [14]; strictly enforcing informed consent and privacy protection clauses for studies involving human subjects [5]; making education and training routine, integrating research integrity education into graduate student programs and continuing education systems for researchers, improving ethical awareness through case studies and simulated ethics reviews, for example, conducting specialized training on issues like data fabrication and improper image processing [23]; balancing incentives and penalties, incorporating integrity performance into core indicators for title promotion, funding allocation, and team excellence evaluations, providing resource support to rigorous scholars, while imposing internal notifications, project termination, and suspension of academic positions on those who violate trustworthiness.

D. Scientific research personnel: Professional self-discipline and responsibility practice

Researchers, as the direct implementers of scientific activities, have professional ethics and ethical awareness that form the foundation of integrity management. The implementation path includes strictly adhering to academic norms, following ethical guidelines throughout the research process from design, data collection to paper writing, and preventing data manipulation, plagiarism, and multiple submissions [4]. Using Electronic Laboratory Notebook (ELN) systems to record the entire research process ensures data integrity and traceability; proactively disclosing conflicts of interest, fully disclosing economic relationships with funding sources and enterprises during paper submission, project application, and technology transfer to avoid biased research conclusions [7], such as requiring corresponding authors to declare whether they serve as corporate advisors or hold relevant patents; socially responsible research, prioritizing social value and safety alongside academic output, for example, strictly adhering to the principles of the Declaration of Helsinki in clinical trials to protect participants' rights [5]; participating in the co-construction of an integrity ecosystem, actively reporting academic misconduct, supporting open data sharing and international cooperation, and promoting a "bottom-up" network of scientific integrity supervision.

This study utilized stakeholder theory to analyze the complex interactions within China's medical research integrity ecosystem and proposed a multi-dimensional collaborative governance framework. The framework aims to enhance accountability, foster synergy among stakeholders, and improve the credibility and sustainability of medical research by clearly articulating the roles and responsibilities of the government, publishing institutions, research institutions, and individual researchers. While the proposed framework offers a normative guide for improving research integrity, its effectiveness relies on robust implementation, continuous evaluation, and the ability to adapt to evolving challenges. Future research should focus on empirical studies to validate the framework's components, assess policy implementation gaps, and develop concrete tools for resolving conflicts of interest and building trust among stakeholders. Further quantitative evidence on misconduct prevalence and the impact of existing policies in China would provide invaluable insights for refining these strategies.

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