

# *Redefining Ethical Boundaries for AI-powered Research? – FAQs on China’s New Measures for Scientific Research and Innovations*

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## **INTRODUCTION**

On October 8, 2023, the Ministry of Science and Technology, in collaboration with nine other national government departments, unveiled the *Measures for Review of Scientific and Technological Ethics (for Trial Implementation)* (the “Measures”). The Measures aims to lay down a solid ethical framework for scientific research and technological development and provide comprehensive and uniform ethical review standards across sectors.

This move was precipitated by concerns voiced by the General Office of the State Council in March 2022 in the office’s efforts to address the intricate challenges of upholding ethical standards in the face of rapid technological progress. Their concerns centered around challenges such as oversight deficiencies and inconsistencies in governance across different science-tech sectors. To address these issues, a range of state and regional governments, including the National Health Commission and Beijing’s and Guangdong’s governments, rolled out their own sectorial or regional science-tech ethical governance initiatives. The introduction of the Measures signifies the commitment on a national level to preserving ethical standards in an era marked by swift technological metamorphosis. This article seeks to answer some key questions regarding the Measures.

### **1. WHAT ARE THE CONDITIONS TRIGGERING SCIENCE-TECH ETHICS REVIEW?**

Article 2 of the Measures outlines four categories of innovative activities that mandate a science-tech ethics review:

- Activities that involve humans as research participants. This encompasses experiments where humans are tested, investigated, observed, or serve in a similar capacity. It also includes activities using human biological samples and personal data;

- Activities that involve experimental animals;
- Activities that, while not directly involving humans or experimental animals, may present ethical risks to life and health, the ecological environment, public order, sustainable development, and so forth;
- Any other activities for which the laws, administrative regulations, or other relevant state rules require a science-tech ethics review.

The reference to “laws, administrative regulations, or other relevant state rules” in the fourth category, at a minimum, includes the following:

- Article 7 of the *Administrative Provisions on Recommendation Algorithms in Internet-based Information Services*, which mandates that recommendation algorithm providers put in place management systems and technical measures dedicated to science-tech ethics review;
- Article 7 of the *Administrative Provisions on Deep Synthesis in Internet-based Information Services*, which requires that deep synthesis service providers establish a robust science-tech ethics review management system;
- Article 8 of the *Implementation Rules for the Regulations on the Management of Human Genetic Resources*, which specifies that any collection, storage, use, and offshore provision of China’s human genetic resources must first pass a science-tech ethics review overseen by qualified science-tech ethics committees; and
- Article 9 of the *Administrative Measures for Personal Information Protection Compliance Audits (Draft for Comment)*, which highlights that for automated decision-making systems processing personal information, an essential component of the compliance audit is to verify if the system’s algorithmic model has passed a science-tech ethics review.

## 2. WHO INITIATES THE SCIENCE-TECH ETHICS REVIEW?

Entities, ranging from higher education academies and research institutes to medical facilities and corporations, bear the primary responsibility for conducting science-tech ethics reviews. Within these entities, the initiation of science-tech reviews typically falls on the shoulders of their designated science-tech ethics committees. To facilitate the process, entities are obligated to equip such committees with the necessary personnel, workspaces, and funding. Moreover, necessary measures must be in place to

ensure that the science-tech ethics committees operate with full autonomy during the review.

In practice, a science-tech ethics committee is indispensable for any entity tasked with such ethical review responsibilities. The Measures stipulates that enterprises involved in fields like life sciences, medicine, and AI have legal obligations to set up such ethics committees. Notably, for AI enterprises hoping to register their algorithms, the presence of an active and functional science-tech ethics committee has become a vital assessment criterion. Furthermore, even for entities without legal obligations to form their own ethics committees, the Measures still advocates for a collaboration approach: these entities are expected to formally delegate their ethics review responsibilities to an already-established and compliant science-tech ethics committee outside their organizations.

### **3. WHAT ARE THE MEASURES REQUIRED FOR THE SCIENCE-TECH ETHICS COMMITTEE?**

The Measures has set forth explicit criteria regarding the set-up of the science-tech ethics committee:

- **Number of Members:** The committee should be composed of at least seven members, which include one chairperson and multiple vice-chairpersons.
- **Background and Diversity:** Members should represent diverse backgrounds and include individuals not affiliated with the entity under review, those of different genders, and preferably individuals familiar with the intricacies of autonomous prefectures of ethnic minorities, particularly if the committee's work concerns those regions.
- **Qualifications:** The committee should comprise professionals familiar with relevant scientific and technological disciplines, alongside experts of ethics and law. All these members are expected to uphold the highest standards of research integrity.
- **Tenure:** Members should serve for a term not exceeding five years, but reappointment for consecutive terms is permissible.

### **4. WHAT DOCUMENTS MUST BE REVIEWED BY THE SCIENCE-**

## TECH ETHICS COMMITTEE?

Article 9 of the Measures specifies six sets of documents that must be furnished to the science-tech ethics committee for review:

- **Activity Profile:** This document should contain the name of the activity under review, its objectives and significance, reasons for the activity, and any prior ethical reviews of the same.
- **Operational Blueprint:** A strategic layout for executing the science-tech activity. This covers the project's blueprint, potential ethical risks, risk mitigation strategies, contingency procedures, and the proposed method for containing ramifications.
- **Organizational Credentials:** Documentation capturing the credentials of all participating bodies, the research experience of involved individuals, details of their past training regarding science-tech ethics, funding origins, and any declarations addressing potential conflicts of interest that may arise from the science-tech activities.
- **Consent & Origins:** An informed consent form, along with descriptions about where biological samples, data sets, and experimental animals (if used) are sourced from.
- **Commitment Letter:** A formal declaration underscoring a commitment to uphold science-tech ethical standards and maintain research integrity.
- **Supplementary Materials:** Any other materials that the science-tech ethics committee deems pertinent for a thorough review.

The decision on whether to proceed with an application rests with the science-tech ethics committee and hinges on the comprehensiveness of the submitted materials. Should there be any gaps or omissions in the submission, the committee shall notify the applicant of all that needs to be supplemented in one single communication.

### 5. WHAT DO DIFFERENT TYPES OF SCIENCE-TECH ETHICS REVIEW PROCEDURES ENTAIL?

There are three types of science-tech ethics review: the Summary Procedure, the Standard Procedure, and the Special Procedure which incorporates an expert second review. Each type varies in the scenario for its application, review panel composition,

the panel’s decision-making mechanism, and frequency of follow-up reviews. A detailed comparison is provided in the table below:

Criteria/Procedure	Summary Procedure	Standard Procedure	Special Procedure
Scenario for Application	<ul style="list-style-type: none"> <li>Any ethical risk of the science-tech activity is considered at most a <b>“minimum risk”</b>.</li> <li>Amendments (if any) made to the approved activity plan are minor and will not alter the risk-benefit ratio of the activity.</li> <li>Follow-up reviews are conducted for previous science-tech activities that have undergone no major alterations.</li> </ul>	Applicable to all science-tech activities not subject to the Summary Procedure.	This procedure is geared toward new science-tech initiatives that potentially carry substantial ethical challenges. The specificities are outlined in the <i>List of Scientific and Technological Activities Requiring Ethical Examination and Review</i> which describes what activities mandate expert second review
Review Panel Makeup	The committee consists of a chair and at least two members selected by the chair.	The review is chaired by the main chairperson or a designated vice chair. The review meeting should have a minimum attendance of five members, representing a broad range of	The preliminary review of this procedure has the same structure as that of the Standard Procedure. At the expert review stage, the panel needs to be made up of at least five specialists, without involving any of the committee

		backgrounds and areas of expertise.	members from the preliminary review.
Decision-making Framework	A unanimous agreement is required. If such unanimous agreement is not achieved, the standard procedure should apply.	Approval of an activity requires the go-ahead from at least two-thirds of the attending members.	At the preliminary stage, at least two-thirds of the attendees need to concur to greenlight an activity. For the ensued expert review, the agreement for the activity must come from no less than two-thirds of the convened experts.
Frequency of Follow-up Review	The committee may adjust the follow-up review intervals as deemed appropriate.	The follow-up review generally should take place at least once every year.	The follow-up review is usually set for at least twice every year.

*\*Minimum risk refers to everyday risks that one might encounter during their daily life or risks comparable to those one might encounter in health checkups.*

The *List of Scientific and Technological Activities Requiring Ethical Examination and Review* (the “List”), as mentioned in the above table, serves as a pivotal reference for the Special Procedure. The List will be maintained and updated from time to time by the Ministry of Science and Technology. Activities specified in the List must first undergo a preliminary review by the science-tech ethics committee. Once the preliminary review is complete, such review then must be reported to either local supervisory bodies or relevant industry regulators for a thorough expert second review.

To determine whether a science-tech activity will be included in the List, the following three key criteria should be considered.

- Inherent ethical risks of the technology, which encompasses the

comprehensiveness of scientific knowledge and the extent of available safety information, as well as the technology's maturity, operability, safety, efficacy, and controllability;

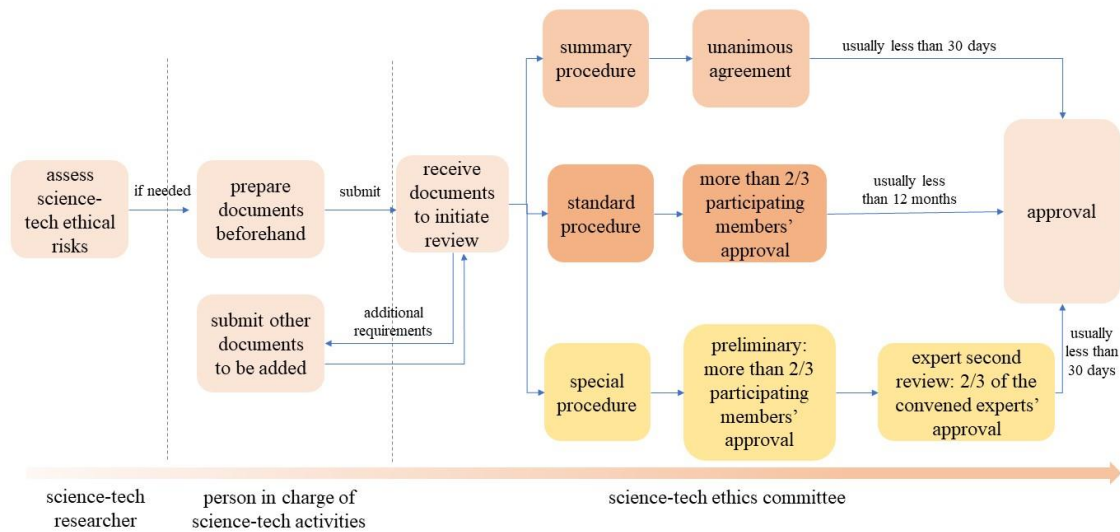
- Factors such as potential ethical risks of the activity, the likelihood of ethical complications, the nature and severity of potential risks, and the extent of their impact;
- Justifiability and necessity of the activity, its intended audience, or target application scenarios, among other factors.

Specifically, according to the Measures, the following activities—when appearing on the List—necessitate an expert second review after the initial ethics review:

- Research focusing on synthesizing new species with potentially far-reaching impacts on human life, health, our ecological environment, or foundational societal values;
- Exploration into the insertion of human stem cells into animal embryos or fetuses and the development of such embryos or fetuses within an animal uterus;
- Fundamental studies into altering the genetic makeup or inheritance processes of human reproductive cells, fertilized ova, or pre-implantation embryonic cells;
- Clinical trials of invasive brain-machine interfaces targeting neurological or psychiatric ailments;
- R&D initiatives centered around human-machine integration systems, which may significantly affect human behavior, emotions, or overall well-being;
- Development of algorithms, applications, or platforms capable of mobilizing public opinion or societal attitudes;
- Design and creation of automated decision-making systems, particularly those with high autonomy, catering to scenarios that present clear safety or health concerns.

## **6. HOW IS EACH PROCEDURE IMPLEMENTED IN PRACTICE?**

Please see the chart below for an overview of the process of science-tech ethics review:



Additionally, the Measures establishes an emergency review procedure for situations like unexpected public emergencies. This streamlined process is designed to complete the science-tech ethical assessment within 72 hours. However, it's noteworthy that although the process is expedited, the robustness of the ethical review standards remains unchanged.

## 7. WHAT CONSTITUTES THE CORE CRITERIA AND STANDARDS FOR SCIENCE-TECH ETHICS REVIEW?

Article 15 of the Measures highlights the key contents and standards of science-tech ethics review as summarized below:

- **Principles:** The proposed science-tech activities should balance innovation with risk management. They should prudently address uncertainties and technology application risks. Activities should align with ethical benchmarks, such as promoting human welfare, respecting life rights, ensuring fairness and transparency, and reasonably managing risks.
- **Personnel:** The qualifications of individuals involved in the science-tech activities should meet the required criteria.
- **Infrastructure:** The underlying research infrastructure and facility conditions should satisfy set standards.
- **Value Proposition:** The proposed activities should offer both scientific and societal value and aim at fostering human well-being and sustainable societal



advancements.

- **Risk Management:** Activities must have a rational risk-benefit profile. Ethical risk mitigation strategies and contingency plans should be in place and should be feasible.
- **Conflict of Interest:** The strategies set for declaring and managing conflicts of interest should be sound and justifiable.

Furthermore, the Measures specifies review priorities for different types of scientific endeavors:

- **Human-centric Research:** Fair participant recruitment, legal and ethical management of biological samples, proper processing of personal privacy data (including biometric information), reasonable remedial and protection plans, clear informed consent processes, and proper care for vulnerable populations are essential. Consent documents should be thorough, clearly articulated, and in full compliance with regulations.
- **Animal-based Research:** Activities should adhere to principles of replacement, reduction, and refinement (the 3Rs). The source and care of animals, including their housing and eventual disposition, should meet animal welfare standards. Adequate safety measures for both practitioners and the public should be in place.
- **Data & Algorithm Research:** Data processing activities and the development of new data technologies should align with national data security and personal information protection standards. Algorithms, models, and systems should respect principles like fairness, transparency, and reliability. Proper ethical risk assessments and user protection measures should be comprehensive and appropriate.

During the expert second review phase, the expert panel primarily focuses on the compliance and rationality of the findings from the preliminary review. This second review verifies whether the preliminary review adheres to China's laws, administrative regulations, relevant state rules, and the ethics of scientific and technological endeavors. It also ensures a thorough, appropriate, and rational assessment of potential ethical risks associated with science-tech activities and their corresponding preventive and control measures.

## **8. HOW IS EXTERNAL OVERSIGHT IMPLEMENTED FOR SCIENCE-TECH ETHICS REVIEW?**

The National Science-Tech Ethics Management Information Registration Platform serves as the primary hub for regulatory bodies to supervise science-tech ethics reviews.

Upon the establishment of a science-tech ethics committee, organizations are legally required to register detailed information about the committee on the National Science-Tech Ethics Management Information Registration Platform within 30 days. The information required to be registered to the platform broadly includes the committee's structure, governing principles, workflows, annual reports, and specifics about its members such as their credentials, roles, and experience in science-tech ethics.

Moreover, the platform is designated for the submission of the committee's annual reports. For science-tech activities that fall under Special Procedure—those included in the List, an additional post-approval registration is required, which requires the science-tech activity's action plan and findings from its ethical review and expert second review processes. Additionally, the registered information should be promptly updated in the case of any changes, and the progress of the science-tech activities should be consistently reported.

While the platform is still under development, once fully operational, it's anticipated to seamlessly integrate with systems like the Public Service Platform of the National Science and Technology Information System, facilitating a more streamlined and collaborative approach to science-tech ethical governance and oversight.

Furthermore, an initiative is underway to introduce a certification mechanism for the science-tech ethics committee, fostering a culture of proactive adherence to science-tech ethics review certification among organizations.

## **9. ARE ENTITIES SUBJECT TO ADDITIONAL RESPONSIBILITIES UNDER THE SCIENCE-TECH MEASURES?**

The Measures requires more than just ethics reviews. It also emphasizes the foundational role of organizational and systematic governance of science-tech activities within enterprises. Key provisions include:

- **Designing and Refining Organizational Protocols:** This includes structuring the science-tech ethics committee management policies, establishing guidelines for expedited ethics reviews during emergencies, and the procedures for oversight, confidentiality, and record-keeping. The goal is to ensure a structured and systematic ethics review process.
- **Regular and Continuous Training:** Such training includes tailored sessions for the science-tech ethics committee, especially training regarding emergency review scenarios, and broader educational initiatives for science-tech professionals, aiming to enhance their understanding and acumen in addressing ethical challenges in the rapidly evolving technological landscape.

## CONCLUSION

The Measures lays out a clear and coherent ethical review framework, streamlining the review procedures while upholding consistent standards. The refined ethical review framework will now emphasize ethical supervision in science-tech initiatives and highlights the importance of risk management. By prioritizing ethical compliance, the Measures seeks to safeguard the welfare of researchers, participants, and the public, and foster the sustainable development of scientific projects and advocate for responsible innovation. Looking forward, the evolving ethical review under the Measures is set to play a pivotal role in advancing China's scientific research and its ethical governance.