Legal Commentary

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China Released New Ethics Rules Requiring Company's Internal EC[1]

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The background of promulgating the *Scientific and Technological Ethics Regulation*

On October 8, 2023, the *Scientific and Technological Ethics Review Regulation (Trial)* ("***Scientific and Technological Ethics Regulation***") was jointly published by the China's Ministry of Science and Technology ("**MOST**"), the Ministry of Education, the Ministry of Industry and Information Technology, and other seven (7) departments/institutions, which was followed by a press conference held next day by the MOST to respond to media inquiries ("**Press Conference**"). The *Scientific and Technological Ethics Regulation* will come into effect on December 1, 2023. Compared to its draft for comments ("***Draft for Comments***") released in April of this year, the promulgation of the final version signals the official landing of many significant compliance systems on scientific ethics (for our interpretation of the *Draft for Comments*, please refer to: *汉坤 • 观点 | 简评《科技伦理审查办法（试行）（征求意见稿）》*). Considering this, we present our analyses on several key issues in the *Scientific and Technological Ethics Regulation* for the purpose of discussion and reference of industry.

The scope of application of the *Scientific and Technological Ethics Regulation*

According to Article 2 of the *Scientific and Technological Ethics Regulation*, the scope of activities subject to the scientific and technological ethics review mainly includes:

- Scientific and technological activities involving humans as research participants, including those using humans as subjects for research activities such as testing, investigation, observation, etc. as well as those scientific and technological activities using human biological samples, personal information data, etc.;
- Scientific and technological activities involving experimental animals;
- Scientific and technological activities that do not directly involve humans or experimental animals, but may pose ethical challenges in areas such as life and health, ecology, public order, sustainable

[1] For the Chinese version, please click *汉坤 • 观点 | 企业或需自设伦理委员会：《科技伦理审查办法（试行）》正式出台*.

[2] Shuwen Sun and Leyi Wang have contributions to this article.

development;

- Other scientific and technological activities that shall be subject to scientific and technological ethics review according to laws, administrative regulations, and national regulations.

In terms of the application scope, the *Scientific and Technological Ethics Regulation* may overlap with the previously issued *Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans*. However, the application of the *Scientific and Technological Ethics Regulation* is wider. As such, with regard to the scientific and technological ethical activities falling under the aforementioned scope, the *Scientific and Technological Ethics Regulation* shall apply in principle. For the field of life science, we understand that the research and development activities involved shall include but are not limited to clinical trials, investigator-initiated clinical trials, real-world research, and some preclinical research.

The applicability relationship between the *Scientific and Technological Ethics Regulation* and relevant rules

Article 54 of the *Scientific and Technological Ethics Regulation* stipulates that if the competent authorities of relevant industries have carried out *lex specialis* in the field of their corresponding industries on the establishment of scientific ethics (review) committees or scientific ethics review in compliance with the spirit of this regulation, the *lex specialis* shall take effect. The Article has provided competent authorities with more discretion in adjusting its intensity of inspection and supervision in accordance with the actual circumstances and provided enterprises with more space for practice, compared with the stipulation of "with the standard no lower than the regulation" in the *Draft for Comments*. Nonetheless, such provision has still not resolved the uncertainties inherent in the applicability relationship between the *Scientific and Technological Ethics Regulation* and other ethics regulations, and the specific standard of review still remains uncertain.

From our understanding, regarding life sciences and medical scientific research activities involving human, the *Scientific and Technological Ethics Regulation* and the *Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans* shall be concurrently applicable, but between both regulations, the *Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans*, and other regulations issued by the healthcare authorities, which also conform to the *Scientific and Technological Ethics Regulation*, may prevail as *lex specialis* of the healthcare industry.

The obligation of establishing a Scientific Ethics Committee

Article 4 of the *Scientific and Technological Ethics Regulation* stipulates that an entity engaged in scientific research activities in **life sciences, medicine, or artificial intelligence**, etc., should establish a scientific ethics (review) committee ("**Scientific Ethics Committee**") if such research falls under **sensitive fields** of scientific ethics. Otherwise, such entities may, but are not obliged to, establish a Scientific Ethics Committee based on their actual needs. Such requirements, initially proposed in the *Draft for Comments*, have officially been implemented. We understand that enterprises involved in the sensitive fields mentioned above and with significant needs for scientific ethics review are obliged to establish the

Scientific Ethics Committees, including but not limited to companies engaged in innovative drug and medical device research and development activities. Other companies are expected to fulfill their duties by bearing responsibilities of scientific ethics management and completing and improving their scientific ethics quality control and regulatory systems. They may decide whether to establish a Scientific Ethics Committee or consider other, more flexible arrangements, such as commissioned reviews. Whether an entity should establish a Scientific Ethics Committee directly relates to whether it involves any research activities in a sensitive field of scientific ethics. However, the regulation and attachments have not clarified the scope of such sensitive fields. The Press Conference made clear that the local authorities of relevant industries will establish their own corresponding supervisory and management systems for scientific ethics review, formulate and revise the corresponding implementing rules and procedures, and establish a system for expert review on the specific scientific activities. We will continue to focus on the following policies and practices set forth in such regulations.

Also, Article 41 of the *Scientific and Technological Ethics Regulation* has provided the accreditation mechanism for the Scientific Ethics Committee, encouraging related enterprises to complete the certification. Such mechanism may effectively solve the problem of the qualification and recognition control of Scientific Ethics Committees.

Scientific and technological ethical review procedure

According to the *Scientific and Technological Ethics Regulation*, the review procedure mainly includes general procedures, simplified procedures, expert review procedures, and emergency procedures. Among them, the expert review procedure is an additional review procedure outside the scientific and technological ethical reviews carried out by the relevant entity itself. Under the *Scientific and Technological Ethics Regulation*, when carrying out scientific and technological activities included in the list maintained by the MOST, after the initial review by the Scientific Ethics Committee, they should apply to the local or relevant industry authorities to conduct expert reviews. For those activities involving multiple industrial institutions, the leading institution should aggregate the information and apply for expert review to the local or relevant industry authorities. A list of emerging technology activities that may pose greater ethical risk challenges will be adjusted as needed and will be published by the MOST. The current list includes:

- Research on the synthesis of new species that have a significant impact on human life, health, values, or the ecological environment, etc.;
- Related research on the introduction of human stem cells into animal embryos or fetuses and further nurturing them into individuals in animal wombs;
- Fundamental research on altering the genetic material or genetic rules of human reproductive cells, fertilized eggs, and pre-implantation embryo cells;
- Clinical research on invasive brain-computer interfaces for the treatment of neurological and mental diseases;
- Research and development of human-machine integration systems with strong impact on human

subjective behavior, emotional psychology, and life health;

- Research and development of algorithm models, applications, and systems with the capability of public opinion mobilization and social consciousness guidance;
- Development of automated decision-making systems with high autonomy for scenarios with safety and personal health risks.

In addition, the *Scientific and Technological Ethics Regulation* has kept the exemption clause of the expert review procedures proposed in the *Draft for Comments*. It stipulates that administrative approvals have been required for certain science and technology activities included in the list management and sets compliance with ethical requirements as the approval conditions and supervision content, there is no need to conduct expert reviews. We understand that clinical trial activities, collection, preservation, international cooperative research and other utilization activities of human genetic resources that are subject to administrative approval and other regulatory procedures may apply the exemption, and there is no need to carry out expert review. The specific scope of application still needs further observations after the *Scientific and Technological Ethics Regulation* comes into effect.

Supervision and administration system and legal responsibility

The *Scientific and Technological Ethics Regulation* states that the MOST is responsible for coordinating and guiding the nation-wide supervision on scientific and technological ethics review regulation. Higher education institutions, research institutions, healthcare and medical institutions, and enterprises are the primal responsible and liable entities for violations to ethics rules.

In addition, the *Scientific and Technological Ethics Regulation* mandates that local and relevant industry authorities, in accordance with their powers, jurisdiction and subordinations, shall investigate and punish ethical misconduct related to science and technology. As per the official interpretation to the *Draft for Comments*, "local authorities" refers to provincial departments responsible for scientific and technological ethical review and administration in relevant fields, and "relevant industry authorities" refer to relevant national industry departments. We understand that relevant industry authorities may have primary jurisdiction over scientific and technological ethical violations related within their respective industries based on their powers and jurisdiction.

As for legal liabilities, compared to the *Draft for Comments*, the *Scientific and Technological Ethics Regulation* has not undergone any significant changes. In addition to criminal and civil liabilities as provided by relevant laws and regulations, the following entities may face administrative penalties for certain violations: those involved in scientific activities who forge ethical approval documents, fail to conduct expert reviews as required, or carry out scientific activities beyond the approved scope; scientific ethics committees or their members who facilitate forgery of ethics approval documents, engage in corruption, abuse of power, or neglect of duties. The *Scientific and Technological Ethics Regulation* does not specify a particular civil, administrative or criminal liability, thus would apply relevant laws and regulations including the *Civil Code*, the *Criminal Law*, and the *Science and Technology Advancement Law* for liabilities. For instance, Article 112 of the *Science and Technology Advancement Law* stipulates that where any scientific and technological professional, in violation of the provisions of this Law, conducts

scientific and technological research, development and application activities that endanger national security, harm public interests, endanger human health, violate scientific integrity and scientific and technological ethics, the employer for which the scientific and technological professional works or the competent authority shall order him/her to make corrections; if there are government funds earmarked for science and technology progress or illegal gains, the competent authority shall terminate or cancel the relevant scientific and technological activities, recover the government funds and confiscate the illegal gains; under serious circumstances, the competent authority shall make illegal acts public, give administrative penalties in accordance with law and prohibit him/her from undertaking or participating in scientific and technological activities supported by government funds and from applying for administrative licenses for scientific and technological activities within a certain period; and the persons directly in charge and other directly liable persons shall be subject to administrative penalty according to law.

Conclusion

The implementation of *Scientific and Technological Ethics Regulation* has further specified the regulatory requirements that enterprises should follow in the field of scientific and technological ethics. In light of this, we suggest that companies potentially involved in sensitive fields of scientific and technological ethics and companies that will have a significant need for scientific and technological ethics review should prepare in advance. In accordance with the *Scientific and Technological Ethics Regulation* and referring to other ethics requirements, they may enhance compliance awareness, and make full use of the time window to make optimal deployment of personnel, policies, and other resources to improve operational compliance.

Important Announcement

This Legal Commentary has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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