Regulations on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies[1]

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Chapter I: General Provisions

Article 1

These Regulations are formulated for the purpose of regulating clinical research and clinical translational application of new biomedical technologies, promoting scientific and technological progress and innovation in medicine, ensuring the quality and safety of medical care, and safeguarding human dignity and health.

Article 2

Entities and individuals engaging in clinical research, clinical translational application, and the supervision and administration thereof, of new biomedical technologies within the territory of the People's Republic of China shall comply with these Regulations.

Article 3

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

For the purposes of these Regulations, "new biomedical technologies" refer to medical professional methods and measures that apply biological principles at the cellular or molecular level to make judgments regarding health status, prevent or treat diseases, or promote health, and that have not yet been applied clinically within the territory of China.

Article 4

The conduct of clinical research and clinical translational application of new biomedical technologies shall adhere to a people-centered approach to health, uphold innovation-driven development, and give equal emphasis to development and safety.

The State shall take measures to promote innovation and development of new biomedical technologies and encourage and support clinical research and clinical translational application of such technologies.

Clinical research and clinical translational application of new biomedical technologies shall be based on scientific evidence, comply with laws, administrative regulations, and relevant national provisions, strengthen safety management throughout the entire process, must not endanger human health, must not violate ethical principles, and must not undermine public interests or national security.

Article 5

Clinical research involving new biomedical technologies shall respect the will of the research participants, uphold their dignity, and protect their lawful rights and interests.

Article 6

The health department of the State Council shall be responsible for the supervision and administration of clinical research and clinical translational application of new biomedical technologies nationwide.

The health departments of local people's governments at or above the county level shall be responsible for the supervision and administration of clinical research and clinical translational application of new biomedical technologies within their respective administrative regions.

Other relevant departments of people's governments at or above the county level shall, within the scope of their respective duties, be responsible for supervision and administration related to clinical research and clinical translational application of new biomedical technologies.

Article 7

Units and individuals that make outstanding contributions in clinical research and clinical translational application of new biomedical technologies shall be commended and rewarded in accordance with relevant State regulations.

Chapter II: Filing for Clinical Research

Article 8

For the purposes of these Regulations, "clinical research of new biomedical technologies" refers to activities conducted to assess the safety and effectiveness of new biomedical technologies and to determine their scope of application, operating procedures, key technical points, and other relevant matters, through any of the following approaches:

1-Conducting operations directly on the human body;

2-Conducting operations on ex vivo cells, tissues, organs, or similar materials, which are subsequently implanted or administered into the human body;

3-Conducting operations on human reproductive cells, zygotes, or embryos, which are subsequently implanted into the human body for development;

4-Other approaches prescribed by the health department of the State Council.

Article 9

Before conducting clinical research involving new biomedical technologies, laboratory studies, animal experiments, and other non-clinical research shall be carried out in accordance with the law. Clinical research may only be initiated after non-clinical research has demonstrated that the technology is safe and effective.

No organization or individual may conduct clinical research on new biomedical technologies that are expressly prohibited by laws, administrative regulations, or relevant national provisions, or that present major ethical concerns.

Article 10

The institution that initiates clinical research on new biomedical technologies (hereinafter referred to as the "clinical research-initiating institution") shall be a legal person lawfully established within the territory of the People's Republic of China.

A clinical research-initiating institution shall ensure that the new biomedical technology proposed for clinical research has been demonstrated through non-clinical studies to be safe and effective.

Article 11

Institutions that conduct clinical research involving new biomedical technologies (hereinafter referred to as “clinical research institutions”) shall meet the following requirements:

1-They are Class III Grade A medical institutions;

2-They have academic committees for clinical research and ethics committees that meet the required standards;

3-They possess qualifications, premises, facilities, equipment, management structures, professional technical personnel, and research capabilities appropriate for the proposed clinical research on new biomedical technologies;

4-They have management systems in place to ensure the quality and safety of clinical research, compliance with ethical principles, and the protection of the lawful rights and interests of research participants;

5-They have stable and sufficient sources of research funding.

Article 12

The clinical research-initiating institution and the clinical research institution shall enter into a written agreement specifying the rights and obligations of both parties, and shall jointly develop the clinical research protocol.

A clinical research institution may also independently initiate clinical research on new biomedical technologies.

Article 13

A clinical research institution shall designate a person responsible for each clinical research project involving new biomedical technologies. The project leader shall hold a medical practitioner’s qualification and a senior professional title, possess good professional ethics, a record of scientific research integrity, and a high level of clinical technical competence, have the professional knowledge, experience, and capability necessary to undertake clinical research on new biomedical technologies, and have the clinical research institution as his or her primary practice institution.

Other personnel participating in clinical research involving new biomedical technologies shall possess the corresponding qualifications, professional knowledge, experience, and capability required.

Article 14

The academic committee and ethics committee of the clinical research institution shall conduct academic review and ethical review, respectively, of the proposed clinical research involving new biomedical technologies in accordance with the relevant requirements. Clinical research may only proceed after passing both academic review and ethical review.

Article 15

Within five working days from the date on which the proposed clinical research involving new biomedical technologies passes academic review and ethical review, the clinical research institution shall file the research with the health department of the State Council.

Where the clinical research-initiating institution initiates the same clinical research project at two or more clinical research institutions, the primary clinical research institution designated by the clinical research-initiating institution shall complete the filing in accordance with the preceding paragraph.

Article 16

To file clinical research involving new biomedical technologies, the following materials shall be submitted:

1-Basic information on the clinical research-initiating institution and the clinical research institution;

2-Basic information on the research personnel;

3-Foundational materials for the clinical research (including summaries of scientific literature, non-clinical research reports, etc.);

4-The clinical research protocol;

5-Possible risks arising from the clinical research and corresponding prevention and control measures, as well as emergency response plans;

6-Academic review opinions and ethical review opinions;

7-The informed consent form (template);

8-Proof of research funding sources and a plan for the use of such funds;

9-Other materials prescribed by the health department of the State Council.

The clinical research institution shall ensure that all submitted materials are true, accurate, and complete.

Article 17

The health department of the State Council shall make public information on filed clinical research projects involving new biomedical technologies, including the clinical research-initiating institutions and clinical research institutions.

The health department of the State Council shall, in accordance with relevant provisions, organize professional institutions to evaluate filed clinical research projects involving new biomedical technologies. If an evaluation identifies technical risks or ethical risks, the health department of the State Council may require the clinical research institution to suspend the clinical research or modify the clinical research protocol. If major technical risks or major ethical risks are identified, the health department of the State Council shall require the clinical research institution to terminate the clinical research.

Chapter III: Implementation of Clinical Research

Article 18

Clinical research institutions shall implement clinical research involving new biomedical technologies in accordance with the filed clinical research protocol. Where it is necessary to modify the clinical research protocol, approval from the academic committee and the ethics committee shall be obtained, and the modification shall be filed with the health department of the State Council within five working days from the date of passing academic and ethical review. However, non-substantive modifications that do not involve the research objectives, research methods, primary endpoints, statistical methods, or research participants are exempt from such filing.

Article 19

Clinical research institutions conducting clinical research involving new biomedical technologies shall obtain the written informed consent of the research participants. If a participant has no capacity for civil conduct or has limited capacity for civil conduct, the written informed consent of the participant's legal guardian shall be obtained in accordance with the law.

Clinical research institutions shall inform participants or their legal guardians of the purpose and protocol of the clinical research in a manner that is easy for them to understand, disclose possible risks, and inform them of their rights. Clinical research institutions must not obtain consent through deception, coercion, or inducement.

Where modifications to the clinical research protocol may affect the rights and interests of the participants, the clinical research institution shall obtain renewed written informed consent from the participants or their legal guardians.

Article 20

Clinical research-initiating institutions and clinical research institutions shall not charge research participants any fees related to clinical research involving new biomedical technologies.

Article 21

Clinical research institutions shall adopt measures to prevent, control, and address risks arising during the implementation of clinical research involving new biomedical technologies.

During the clinical research process, all operations performed on the human body shall be carried out by health professionals holding appropriate qualifications. Any pharmaceuticals or medical devices used must comply with the *Drug Administration Law of the People's Republic of China*, the *Regulations on the Supervision and Administration of Medical Devices*, and other relevant laws and administrative regulations.

Article 22

Clinical research institutions shall promptly, accurately, and fully record the implementation of clinical research involving new biomedical technologies and retain relevant original materials. Records and original materials shall be preserved for 30 years from the conclusion of the clinical research; where the clinical research involves descendants, records and original materials shall be preserved permanently.

Clinical research-initiating institutions and clinical research institutions shall not fabricate, tamper with, or conceal records or original materials related to clinical research involving new biomedical technologies.

Article 23

Where a clinical research institution requires another institution to provide technical support for the implementation of clinical research involving new biomedical technologies, to supply biological samples such as human cells, tissues, or organs, or to assist in recruiting participants, it shall inform such institution of the purpose and protocol of the clinical research, its filing status, and the intended use of the biological samples.

Article 24

Clinical research institutions shall periodically report the implementation status of clinical research involving new biomedical technologies to the health department of the State Council.

Article 25

Under any of the following circumstances, the clinical research institution shall terminate the clinical research involving new biomedical technologies, report the matter to the health department of the State Council within five working days, and inform the clinical research-initiating institution:

1-Major issues are discovered regarding the safety or effectiveness of the new biomedical technology;

2-The clinical research has caused or may cause significant adverse social impact;

3-Uncontrollable risks arise during the clinical research process;

4-Other circumstances prescribed by the health department of the State Council.

Where serious adverse reactions occur during clinical research involving new biomedical technologies, the clinical research institution shall suspend the clinical research, and the ethics committee of the clinical research institution shall evaluate whether the research may continue. Based on the evaluation conclusions, the clinical research institution shall either terminate or continue the clinical research and shall report the decision to the health department of the State Council within five working days, while also informing the clinical research-initiating institution.

Article 26

Upon completion of clinical research involving new biomedical technologies, the clinical research institution shall report to the health department of the State Council on the implementation of the clinical research, the research results, and recommendations for clinical translational application. The clinical research institution shall conduct follow-up monitoring of the research participants to assess the long-term safety and effectiveness of the new biomedical technology.

Article 27

Where clinical research involving new biomedical technologies causes harm to the health of research participants, the clinical research institution shall provide timely medical treatment. The medical treatment expenses shall be borne by the clinical research-initiating institution; however, where the harm to the participants' health results from the fault of the clinical research institution, the medical treatment expenses shall be borne by the clinical research institution.

Clinical research-initiating institutions and clinical research institutions are encouraged to provide appropriate protection for research participants by purchasing commercial insurance.

Article 28

Clinical research-initiating institutions, clinical research institutions, and other institutions involved in clinical research involving new biomedical technologies shall protect the personal privacy and personal information of research participants in accordance with the law.

Chapter IV: Clinical Translational Application

Article 29

Where a new biomedical technology is intended for clinical translational application following the completion of its clinical research, it shall be subject to review and approval by the health department of the State Council.

Article 30

Where a new biomedical technology is intended for clinical translational application, the clinical research-initiating institution shall submit an application to the health department of the State Council and provide the following materials:

1-The clinical research report and records of the new biomedical technology;

2-The scope of application of the new biomedical technology, as well as possible adverse reactions and contraindications;

3-The conditions that medical institutions and health professionals must meet in order to apply the new biomedical technology;

4-Operating specifications for clinical application;

5-Possible risks arising from clinical application and corresponding prevention and control measures;

6-Other materials prescribed by the health department of the State Council.

The clinical research-initiating institution shall ensure that all submitted materials are truthful, accurate, and complete.

Article 31

The health department of the State Council shall, within five working days from the date it accepts an application for clinical translational application of a new biomedical technology, forward the application materials to professional institutions for technical and ethical

evaluations. The health department of the State Council shall make a decision within fifteen working days from the date of receiving the evaluation opinions. Approval shall be granted for technologies proven through clinical research to be safe and effective and in compliance with ethical principles; for those that do not meet these requirements, approval shall not be granted, and written reasons shall be provided.

The regulatory norms for reviewing applications for clinical translational application of new biomedical technologies, as well as the rules governing technical evaluations and ethical evaluations, shall be formulated by the health department of the State Council.

Article 32

For applications for clinical translational application of new biomedical technologies intended to treat diseases that are severely life-threatening and for which no effective treatment exists, or for technologies urgently needed in the field of public health, the health department of the State Council shall give priority to review and approval.

Article 33

Where the health department of the State Council approves the clinical translational application of a new biomedical technology, it shall make public the name of the technology, the conditions that medical institutions and health professionals must meet to apply the technology, and the operating specifications for its clinical application.

Article 34

Medical institutions applying a new biomedical technology that has been approved for clinical translational application shall meet the conditions prescribed by the health department of the State Council. Medical institutions and their medical personnel shall comply with the operating specifications for the clinical application of the technology, ensure the quality and safety of medical care, and prevent and control risks. Medical institutions may charge fees for such clinical applications in accordance with relevant regulations.

Article 35

Medical institutions shall report the clinical application of new biomedical technologies approved for clinical translational application to the health department of the people's government of the province, autonomous region, or municipality directly under the Central Government where the institution is located, in accordance with the provisions of the health department of the State Council. Where serious adverse reactions or medical incidents occur

during clinical application, medical institutions shall handle such matters in accordance with relevant regulations.

Article 36

To respond to extraordinarily significant public health emergencies or other urgent incidents that pose a grave threat to public health, the health department of the State Council may, upon organized evaluation and where it is deemed necessary, authorize the emergency use of new biomedical technologies that are still undergoing clinical research, within a prescribed scope and for a limited period.

Article 37

If a biomedical new technology approved for clinical translation and application meets any of the following conditions, the competent health authority under the State Council shall re-evaluate its safety and effectiveness. During the re-evaluation, clinical use of the technology shall be suspended:

1-Scientific developments lead to changes in the understanding of the safety or effectiveness of the technology;

2-Serious adverse reactions occur or uncontrollable risks emerge during clinical application;

3-Other circumstances as prescribed by the competent health authority under the State Council.

If the re-evaluation determines that the technology cannot be guaranteed to be safe and effective, the competent health authority under the State Council shall decide to prohibit its clinical application.

Chapter V: Supervision and Administration

Article 38

Health authorities of people's governments at or above the county level shall supervise and inspect biomedical new technology clinical studies and clinical translation applications. Any conduct in violation of these Regulations shall be handled in accordance with the law.

Article 39

When conducting supervision and inspection, health authorities of people's governments at or above the county level may take the following measures:

1-Conduct on-site inspections of locations where biomedical new technology clinical studies or clinical applications are carried out;

2-Review and copy relevant records, medical files, agreements, receipts, accounting books, and other materials;

3-Seal or seize equipment, drugs, medical devices, and other items suspected of being used to carry out biomedical new technology clinical studies or applications in violation of the law;

4-Seal locations or facilities suspected of being used to carry out biomedical new technology clinical studies or applications in violation of the law.

Entities subject to inspection shall cooperate with supervision and inspection and shall not refuse or conceal relevant information.

Article 40

The competent authorities of scientific research institutions, educational institutions, and other sponsors of clinical studies shall strengthen the management of such clinical study sponsors and cooperate with the health authorities in conducting supervision and inspection related to biomedical new technologies. Any conduct found to violate the provisions of these Regulations shall be promptly reported to the health authorities at the same administrative level.

Article 41

The competent health authority under the State Council shall establish an online service system for biomedical new technology clinical research and clinical translation applications, facilitating clinical study sponsors, clinical research institutions, and other relevant entities in registration, administrative license applications, and information reporting. Health authorities of people's governments at or above the county level shall, through the online service system, promptly disclose information on registrations, administrative licenses, supervision and inspection, and the handling of violations.

The competent health authority under the State Council shall guide professional institutions to strengthen capacity building and enhance the professional level of evaluations.

Article 42

Health authorities of people's governments at or above the county level shall publicly disclose their email addresses and telephone numbers to receive complaints and reports and shall handle them promptly. Verified reports shall be rewarded in accordance with relevant national provisions.

Health authorities of people's governments at or above the county level shall keep the information of whistleblowers confidential and protect their legitimate rights and interests.

Chapter VI: Legal Liability

Article 43

Anyone who violates the provisions of Paragraph 2, Article 9 of these Regulations by conducting prohibited biomedical new technology clinical research, or by applying such prohibited technologies in clinical practice, shall be ordered by the health authorities of people's governments at or above the county level to cease the illegal activity and shall have any illegal gains, related records, and items confiscated.

If there are no illegal gains or if the illegal gains are less than RMB 1,000,000, a fine of not less than RMB 1,000,000 but not more than RMB 10,000,000 shall be imposed;If the illegal gains exceed RMB 1,000,000, a fine of 10 to 20 times the illegal gains shall be imposed.

In addition, the entity shall be prohibited from conducting biomedical new technology clinical research for a period of five years. The original licensing authority may revoke the medical institution's practice license or order the suspension of its operations.

Responsible leadership and directly accountable personnel shall be subject to disciplinary actions according to law, a fine of RMB 100,000 to 200,000, and a prohibition from engaging in biomedical new technology clinical research for a period of 10 years up to a lifetime. The original registration authority shall revoke the professional licenses of the relevant medical personnel.

Article 44

In any of the following circumstances, the health authorities of people's governments at or above the county level shall order the cessation of illegal activities, confiscate illegal gains and related records and items, and impose penalties:

1-If there are no illegal gains or the illegal gains are less than RMB 1,000,000, a fine of RMB 500,000 to 5,000,000 shall be imposed;

2-If the illegal gains exceed RMB 1,000,000, a fine of 5 to 10 times the illegal gains shall be imposed.

The entity shall be prohibited from conducting biomedical new technology clinical research for a period of three years. The original licensing authority may revoke the medical institution's practice license or order suspension of operations.

Responsible leadership and directly accountable personnel shall be subject to disciplinary actions according to law, a fine of RMB 20,000 to 100,000, a prohibition from engaging in biomedical new technology clinical research for a period of five years, and the original registration authority shall revoke the professional licenses of the relevant medical personnel.

These circumstances include:

1-Conducting clinical research on biomedical new technologies that have not been proven safe and effective through preclinical studies;

2-Conducting biomedical new technology clinical research without passing academic review or ethical review;

3-Applying biomedical new technologies in clinical practice without approval for clinical translation.

Article 45

If biomedical new technology clinical research is conducted in violation of Paragraph 1, Article 10, or Article 11 of these Regulations, the health authorities of people's governments at or above the county level shall order the cessation of the clinical research, confiscate illegal gains and related records and items, and impose a fine of RMB 200,000 to 1,000,000. The entity shall be prohibited from conducting biomedical new technology clinical research for a period of two years.

Responsible leadership and directly accountable personnel shall be subject to disciplinary actions in accordance with the law, a fine of RMB 10,000 to 50,000, and a prohibition from engaging in biomedical new technology clinical research for a period of three years.

If biomedical new technology clinical research is conducted without registration as required by these Regulations, the health authorities of people's governments at or above the county level shall order registration within a prescribed period. If registration is not completed within the prescribed period, penalties shall be imposed in accordance with the preceding paragraph.

Article 46

In any of the following circumstances, the health authorities of people's governments at or above the county level shall order the cessation of biomedical new technology clinical research and impose a fine of RMB 100,000 to 500,000.

Responsible leadership and directly accountable personnel shall be subject to disciplinary actions in accordance with the law, a fine of RMB 10,000 to 30,000, and a prohibition from engaging in biomedical new technology clinical research for a period of two years. Relevant medical personnel shall be ordered to suspend their practice for a period of six months to one year, or their professional licenses may be revoked by the original registration authority.

These circumstances include:

1-Clinical research institutions fail to suspend clinical research, amend clinical research protocols, or terminate clinical research as required by the competent health authority under the State Council;

2-Clinical research institutions fail to obtain written informed consent from subjects or their guardians in accordance with Article 19 of these Regulations;

3-Clinical study sponsors or clinical research institutions falsify, alter, or conceal records or original materials of biomedical new technology clinical research;

4-Clinical research institutions fail to terminate biomedical new technology clinical research in accordance with Article 25 of these Regulations.

Article 47

In any of the following circumstances, the health authorities of people's governments at or above the county level shall order correction within a specified period, impose a fine of RMB 50,000 to 200,000, and may order the suspension of biomedical new technology clinical research.

If the circumstances are serious, the authorities may order the cessation of clinical research and impose a fine of RMB 200,000 to 500,000. Responsible leadership and directly accountable personnel shall be subject to disciplinary actions according to law, a fine of RMB 10,000 to 30,000, and a prohibition from engaging in biomedical new technology clinical research for a period of two years.

These circumstances include:

1-Clinical research institutions fail to conduct biomedical new technology clinical research in accordance with the registered clinical research protocol, except for non-substantive changes to the protocol;

2-Clinical research institutions fail to implement risk prevention, control, or mitigation measures as required under Paragraph 1, Article 21 of these Regulations;

3-Clinical research institutions assign personnel who do not possess the required qualifications to perform operations on human subjects, in violation of Paragraph 2, Article 21 of these Regulations;

4-Clinical research institutions fail to provide treatment to subjects in accordance with Paragraph 1, Article 27 of these Regulations, or otherwise infringe upon the legitimate rights and interests of subjects.

Article 48

In any of the following circumstances, the health authorities of people's governments at or above the county level shall order correction within a specified period and may order the suspension of biomedical new technology clinical research. If the circumstances are serious, the authorities may order the cessation of clinical research. Responsible leadership and directly accountable personnel shall be subject to disciplinary actions according to law:

1-Clinical research institutions fail to record the implementation of clinical research and retain original materials in accordance with Paragraph 1, Article 22 of these Regulations;

2-Clinical research institutions fail to provide the required notifications in accordance with Article 23 of these Regulations;

3-Clinical research institutions fail to report the implementation of clinical research in accordance with Article 24 of these Regulations.

If clinical research institutions fail to report as required under Articles 25 and 26 of these Regulations, or if medical institutions fail to report as required under Article 35 of these Regulations, the health authorities of people's governments at or above the county level shall order correction within a prescribed period. If the correction is not made within the prescribed period, a fine of RMB 20,000 to 50,000 shall be imposed.

Article 49

If clinical study sponsors or clinical research institutions collect fees from subjects in connection with biomedical new technology clinical research, the market supervision authorities of people's governments at or above the county level shall order the refund of such fees and may impose a fine of up to five times the illegally collected amount. In serious cases, the authorities may order the suspension of operations for rectification.

Article 50

If a medical institution that does not meet the conditions prescribed by the competent health authority under the State Council conducts clinical application of a biomedical new technology that has been approved for clinical translation, the health authorities of people's governments at or above the county level shall order the cessation of such clinical application, confiscate any illegal gains, and impose a fine of RMB 100,000 to 500,000. In serious cases, a fine of RMB 500,000 to 1,000,000 may be imposed.

Article 51

If a clinical study sponsor provides false information or uses other fraudulent means when applying for a biomedical new technology clinical translation application license, the application shall not be accepted or the administrative license shall not be granted. If the administrative license has already been granted, the competent health authority under the State Council shall revoke the license, confiscate any illegal gains, impose a fine of 5 to 10 times the illegal gains, and prohibit the entity from conducting biomedical new technology clinical research for a period of three years. Responsible leadership and directly accountable personnel shall be subject to disciplinary actions in accordance with the law, a fine of RMB 20,000 to 100,000, and a prohibition from engaging in biomedical new technology clinical research for a period of five years.

If a clinical research institution provides false information or uses other fraudulent means during biomedical new technology clinical research registration, the competent health authority under the State Council shall order the cessation of clinical research, confiscate illegal gains and relevant records and items, impose a fine of 2 to 5 times the illegal gains, and prohibit the entity from conducting biomedical new technology clinical research for a period of two years. Responsible leadership and directly accountable personnel shall be subject to disciplinary actions in accordance with the law, a fine of RMB 10,000 to 50,000, and a prohibition from engaging in biomedical new technology clinical research for a period of three years.

Article 52

If a professional institution issues false evaluation opinions during an assessment, the health authorities of people's governments at or above the county level shall impose a fine of RMB 100,000 to 500,000 and prohibit the institution from participating in biomedical new technology–related assessment work for a period of three years. Responsible leadership and directly accountable personnel shall be subject to disciplinary actions in accordance with law, a fine of RMB 10,000 to 50,000, and a prohibition from participating in biomedical new technology–related assessment work for a period of five years.

Article 53

Health, medical, and related department personnel who violate the provisions of these Regulations by abusing their authority, neglecting their duties, or engaging in favoritism or corruption shall be subject to disciplinary actions according to law.

Article 54

Any violation of these Regulations that causes personal injury or property damage shall entail civil liability in accordance with law. If the act constitutes a crime, criminal responsibility shall be pursued in accordance with law.

Chapter VII: Supplementary Provisions

Article 55

Clinical trials conducted for the development of drugs or medical devices shall comply with the provisions of the *Drug Administration Law of the People's Republic of China*, the *Regulations on the Supervision and Administration of Medical Devices*, and other relevant laws and administrative regulations.

The competent health authority under the State Council, in conjunction with the State Drug Administration, shall formulate and adjust guidance principles for defining the scope of biomedical new technologies in relation to drugs and medical devices in accordance with developments in science and technology.

Article 56

Military medical institutions conducting biomedical new technology clinical research and clinical translation applications shall be supervised and managed by the relevant departments of the Central Military Commission with reference to the provisions of these Regulations.

Article 57

Biomedical new technology clinical research already underway before the implementation of these Regulations may continue in accordance with the approved clinical research protocol. Clinical research institutions shall complete registration in accordance with these Regulations within one month from the date of their implementation.

Article 58

These Regulations shall come into force on May 1, 2026.