Regulations on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies of China (the PRC)

Dan Young Business Consultancy — www.danyoungcpa.com

Unofficial English translation prepared for reference only. The official Chinese text prevails.

Contents

Table of Contents 1

Chapter I — General Provisions 1

Chapter II — Filing of Clinical Research 2

Chapter III — Implementation of Clinical Research 4

Chapter IV — Clinical Translational Application 6

Chapter V — Supervision and Administration 7

Chapter VI — Legal Liability 8

Chapter VII — Supplementary Provisions 11

Adopted at the 68th Executive Meeting of the State Council on September 12, 2025, promulgated by Order No. 818 of the State Council of the People's Republic of China on September 28, 2025, and effective as of May 1, 2026

Table of Contents

- Chapter I — General Provisions
- Chapter II — Filing of Clinical Research
- Chapter III — Implementation of Clinical Research
- Chapter IV — Clinical Translational Application
- Chapter V — Supervision and Administration
- Chapter VI — Legal Liability
- Chapter VII — Supplementary Provisions

Chapter I — General Provisions

Article 1 — These Regulations are formulated to standardize the clinical research and clinical translational application of new biomedical technologies, promote the progress and innovation of medical science and technology, safeguard medical quality and safety, and uphold human dignity and health.

Article 2 — Persons engaging in the clinical research and clinical translational application of new biomedical technologies, and the supervision and administration thereof, within the territory of the People's Republic of China shall comply with these Regulations.

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

Article 3 — For the purposes of these Regulations, "new biomedical technologies" means professional medical means and measures that apply biological principles at the cellular and molecular level of the human body, for the purpose of assessing health status or preventing or treating diseases and promoting health, and that have not yet been applied clinically within the territory of China.

Article 4 — The clinical research and clinical translational application of new biomedical technologies shall adhere to a people's health-centered approach, adhere to innovation-driven development, and attach equal importance to development and safety.

The State takes measures to promote the innovative development of new biomedical technologies, and encourages and supports the clinical research and clinical translational application of new biomedical technologies.

The clinical research and clinical translational application of new biomedical technologies shall have a scientific basis, comply with laws, administrative regulations and the relevant provisions of the State, strengthen whole-process safety management, shall not endanger human health, shall not violate ethical principles, and shall not harm the public interest or national security.

Article 5 — The clinical research of new biomedical technologies shall respect the will of research subjects, uphold their dignity, and protect their lawful rights and interests.

Article 6 — The health commission of the State Council is responsible for the supervision and administration of the clinical research and clinical translational application of new biomedical technologies nationwide.

The health commissions of local people's governments at or above the county level are responsible for the supervision and administration of the 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 are responsible, within the scope of their respective duties, for the supervision and administration related to the clinical research and clinical translational application of new biomedical technologies.

Article 7 — Units and individuals that have made outstanding contributions to the clinical research and clinical translational application of new biomedical technologies shall be commended and rewarded in accordance with the relevant provisions of the State.

Chapter II — Filing of Clinical Research

Article 8 — For the purposes of these Regulations, "clinical research of new biomedical technologies" means activities that test new biomedical technologies, by the following means, to determine their safety and efficacy and to clarify their scope of application, operating procedures, technical essentials and the like:

(1) operating directly on the human body;

(2) operating on ex vivo cells, tissues, organs or the like, and subsequently implanting or transfusing them into the human body;

(3) operating on human germ cells, zygotes or embryos, and subsequently implanting them into the human body for development; or

(4) other means prescribed by the health commission of the State Council.

Article 9 — Before conducting clinical research of a new biomedical technology, non-clinical research such as laboratory research and animal experiments shall be conducted in accordance with the law; only after the technology has been proven safe and effective through non-clinical research may clinical research be conducted.

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

No organization or individual may conduct clinical research on new biomedical technologies that are expressly prohibited by laws, administrative regulations and the relevant provisions of the State, or that involve major ethical issues.

Article 10 — The institution initiating clinical research of a new biomedical technology (hereinafter the "clinical research initiating institution") shall be a legal person established in accordance with the law within the territory of China.

The clinical research initiating institution shall ensure that the new biomedical technology for which clinical research is to be conducted has been proven safe and effective through non-clinical research.

Article 11 — The institution implementing clinical research of a new biomedical technology (hereinafter the "clinical research institution") shall meet the following conditions:

(1) being a Grade III Class A medical institution;

(2) having an academic committee for clinical research and an ethics committee that meet the requirements;

(3) having the qualifications, premises, facilities, equipment, management bodies, professional technical personnel and research capabilities commensurate with the clinical research of the new biomedical technology to be conducted;

(4) having management systems that ensure the quality and safety of clinical research, comply with ethical principles and protect the lawful rights and interests of research subjects; and

(5) having a stable and sufficient source of research funds.

Article 12 — The clinical research initiating institution and the clinical research institution shall enter into a written agreement, stipulating the rights and obligations of both parties, and jointly formulate the clinical research plan.

The clinical research institution may also initiate clinical research of a new biomedical technology on its own.

Article 13 — The clinical research institution shall designate a person in charge of the clinical research project of the new biomedical technology. The project person in charge shall hold a medical practitioner qualification and a senior professional title, have good professional ethics, scientific research credibility and clinical technical competence, possess the professional knowledge, experience and capability required to undertake clinical research of the new biomedical technology, and have the clinical research institution as his or her primary practice institution.

Other personnel participating in clinical research of the new biomedical technology shall have the corresponding qualifications, professional knowledge, experience and capabilities.

Article 14 — The academic committee for clinical research and the ethics committee of the clinical research institution shall conduct academic review and ethical review of the proposed clinical research of the new biomedical technology in accordance with the provisions; only after the clinical research passes academic review and ethical review may it be conducted.

Article 15 — The clinical research institution shall file with the health commission of the State Council within five working days from the date the clinical research of the new biomedical technology passes academic review and ethical review.

Where the clinical research initiating institution initiates the same clinical research of a new biomedical technology at two or more clinical research institutions, the primary clinical research institution selected by the clinical research initiating institution shall file in accordance with the preceding paragraph.

Article 16 — To file clinical research of a new biomedical technology, the following materials shall be submitted:

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

(1) the basic information of the clinical research initiating institution and the clinical research institution;

(2) the basic information of the research personnel;

(3) the basis for the clinical research (including scientific literature summaries and non-clinical research reports);

(4) the clinical research plan;

(5) the risks that may arise from the clinical research and the measures for their prevention and control and the emergency response plan;

(6) the academic review opinions and ethical review opinions;

(7) the informed consent form (sample);

(8) the proof of the source of research funds and the plan for their use; and

(9) other materials prescribed by the health commission of the State Council.

The clinical research institution shall ensure that the submitted materials are authentic, accurate and complete.

Article 17 — The health commission of the State Council shall publish the filed clinical research of new biomedical technologies and information on the clinical research initiating institutions and clinical research institutions.

The health commission of the State Council shall, in accordance with the provisions, organize professional institutions to evaluate the filed clinical research of new biomedical technologies. Where, upon evaluation, the clinical research involves technical risks or ethical risks, the health commission of the State Council may require the clinical research institution to suspend the clinical research or change the clinical research plan; where the clinical research involves major technical risks or major ethical risks, the health commission of the State Council shall require the clinical research institution to terminate the clinical research.

Chapter III — Implementation of Clinical Research

Article 18 — The clinical research institution shall implement clinical research of the new biomedical technology in accordance with the filed clinical research plan. Where it is truly necessary to change the clinical research plan, the change shall be subject to review and approval by the academic committee for clinical research and the ethics committee, and a filing of change shall be made with the health commission of the State Council within five working days from the date of passing academic review and ethical review, except for non-substantive changes that do not involve the research purpose, research methods, primary endpoints, statistical methods or research subjects.

Article 19 — The clinical research institution shall obtain written informed consent from the research subjects when implementing clinical research of the new biomedical technology. Where a research subject is a person without capacity for civil conduct or a person with limited capacity for civil conduct, written informed consent shall be obtained from his or her guardian in accordance with the law.

The clinical research institution shall inform the research subject or his or her guardian of the purpose and plan of the clinical research in a manner easy to understand, disclose the risks that may arise, and inform the research subject of the rights and interests he or she enjoys. The clinical research institution shall not obtain the consent of the research subject or his or her guardian by deception, coercion or inducement.

Where a change in the clinical research plan may affect the rights and interests of the research subject, the clinical research institution shall re-obtain written informed consent from the research subject or his or her guardian.

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

Article 20 — The clinical research initiating institution and the clinical research institution shall not charge research subjects any fees related to the clinical research of the new biomedical technology.

Article 21 — The clinical research institution shall take measures to prevent, control and handle risks arising during the implementation of clinical research of the new biomedical technology.

In the course of clinical research of the new biomedical technology, operations on the human body shall be carried out by health professional technical personnel with the corresponding qualifications; the drugs and medical devices used shall comply with the provisions of laws and administrative regulations such as the Drug Administration Law of the People's Republic of China and the Regulations on the Supervision and Administration of Medical Devices.

Article 22 — The clinical research institution shall promptly, accurately and completely record the implementation of clinical research of the new biomedical technology and retain the relevant original materials. Records and original materials shall be preserved for 30 years from the end of the clinical research; where the clinical research involves offspring, the records and original materials shall be preserved permanently.

The clinical research initiating institution and the clinical research institution shall not forge, alter or conceal clinical research records and original materials of the new biomedical technology.

Article 23 — Where the clinical research institution needs another institution to provide technical support for its implementation of clinical research of the new biomedical technology, to provide biological samples such as human cells, tissues or organs, or to assist in recruiting research subjects, it shall inform the purpose and plan of the clinical research, the filing status and the use of the biological samples.

Article 24 — The clinical research institution shall periodically report the implementation of clinical research of the new biomedical technology to the health commission of the State Council.

Article 25 — Under any of the following circumstances, the clinical research institution shall terminate clinical research of the new biomedical technology, report to the health commission of the State Council within five working days, and inform the clinical research initiating institution:

(1) major problems are discovered in the safety or efficacy of the new biomedical technology;

(2) the clinical research causes or may cause major adverse social impact;

(3) uncontrollable risks arise during the clinical research; or

(4) other circumstances prescribed by the health commission of the State Council.

Where a serious adverse reaction occurs during clinical research of the new biomedical technology, the clinical research institution shall suspend the clinical research, and the clinical research ethics committee shall evaluate whether the clinical research may continue. The clinical research institution shall terminate or continue the clinical research based on the evaluation opinions, report to the health commission of the State Council within five working days, and inform the clinical research initiating institution.

Article 26 — After the completion of clinical research of the new biomedical technology, the clinical research institution shall report the implementation of the clinical research, the research results and the recommendations for clinical translational application to the health commission of the State Council. The clinical research institution shall conduct follow-up monitoring of research subjects and evaluate the long-term safety and efficacy of the new biomedical technology.

Article 27 — Where clinical research of a new biomedical technology causes health damage to a research subject, the clinical research institution shall provide timely treatment, and the treatment costs shall be borne by the clinical research initiating institution; however, where the health damage to the research subject is caused by the fault of the clinical research institution, the treatment costs shall be borne by the clinical

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

research institution.

The clinical research initiating institution and the clinical research institution are encouraged to provide corresponding safeguards for research subjects through the purchase of commercial insurance.

Article 28 — The clinical research initiating institution, the clinical research institution and other institutions related to clinical research of the new biomedical technology shall protect the personal privacy and personal information of research subjects in accordance with the law.

Chapter IV — Clinical Translational Application

Article 29 — Where a new biomedical technology is to be applied clinically through translation after the completion of clinical research, it shall be subject to review and approval by the health commission of the State Council.

Article 30 — Where a new biomedical technology is to be applied clinically through translation, the clinical research initiating institution shall apply to the health commission of the State Council and submit the following materials:

(1) the clinical research report and records of the new biomedical technology;

(2) the scope of application, possible adverse reactions and contraindications of the new biomedical technology;

(3) the conditions required of the medical institutions and health professional technical personnel applying the new biomedical technology;

(4) the clinical application operating specifications;

(5) the risks that may arise in clinical application and the measures for their prevention and control; and

(6) other materials prescribed by the health commission of the State Council.

The clinical research initiating institution shall ensure that the submitted materials are authentic, accurate and complete.

Article 31 — The health commission of the State Council shall, within five working days from the date of acceptance of the application for clinical translational application of the new biomedical technology, transfer the application materials to a professional institution for technical evaluation and ethical evaluation, and make a decision within 15 working days from the date of receipt of the evaluation opinions. Where the clinical research has proven the technology to be safe and effective and the technology complies with ethical principles, approval shall be granted; where it does not meet the above requirements, approval shall not be granted and the reasons shall be stated in writing.

The work norms for the review of clinical translational application of new biomedical technologies and the work rules for technical evaluation and ethical evaluation shall be formulated by the health commission of the State Council.

Article 32 — For applications for clinical translational application of new biomedical technologies for the treatment of serious life-threatening diseases for which there is no effective treatment, and of new biomedical technologies urgently needed for public health, the health commission of the State Council shall give priority review and approval.

Article 33 — Where the health commission of the State Council approves the clinical translational application of a new biomedical technology, it shall publish the name of the technology, the conditions required of the medical institutions and health professional technical personnel applying the technology, and the clinical application operating specifications.

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

Article 34 — For a new biomedical technology whose clinical translational application has been approved, a medical institution conducting clinical application shall meet the conditions prescribed by the health commission of the State Council. The medical institution and its medical personnel shall comply with the clinical application operating specifications of the technology, safeguard medical quality and safety, and prevent and control risks. The medical institution may charge fees for clinical application in accordance with the provisions.

Article 35 — A medical institution shall, in accordance with the provisions of the health commission of the State Council, report the clinical application of a new biomedical technology whose clinical translational application has been approved to the health commission of the people's government of the province, autonomous region or municipality directly under the Central Government at its location. Where a serious adverse reaction or a medical accident occurs during clinical application, the medical institution shall handle it in accordance with the provisions.

Article 36 — To respond to extraordinarily serious public health emergencies or other emergencies that seriously threaten public health, the health commission of the State Council may, where it deems it truly necessary after organized demonstration, approve the emergency application, within a certain scope and period, of a new biomedical technology that is undergoing clinical research.

Article 37 — Where a new biomedical technology whose clinical translational application has been approved falls under any of the following circumstances, the health commission of the State Council shall re-evaluate its safety and efficacy, and suspend clinical application of the technology during the re-evaluation period:

(1) based on the development of scientific research, there is a change in the understanding of the safety and efficacy of the technology;

(2) a serious adverse reaction or uncontrollable risk occurs during clinical application; or

(3) other circumstances prescribed by the health commission of the State Council.

Where it is determined through evaluation that safety and efficacy cannot be guaranteed, the health commission of the State Council shall decide to prohibit clinical application of the technology.

Chapter V — Supervision and Administration

Article 38 — The health commissions of people's governments at or above the county level shall supervise and inspect the clinical research and clinical translational application of new biomedical technologies; where violations of these Regulations are discovered, they shall be handled in accordance with the law.

Article 39 — When conducting supervision and inspection, the health commissions of people's governments at or above the county level may take the following measures:

(1) entering premises for clinical research or clinical application of new biomedical technologies to conduct on-site inspection;

(2) consulting and copying relevant records, medical records, agreements, bills, account books and other materials;

(3) sealing up or seizing equipment, drugs, medical devices and other items suspected of being used for illegal clinical research or clinical application of new biomedical technologies; and

(4) sealing up premises and facilities suspected of being used for illegal clinical research or clinical application of new biomedical technologies.

The inspected units shall cooperate with supervision and inspection and shall not refuse or conceal.

Article 40 — The competent departments of clinical research initiating institutions such as scientific research institutions and educational institutions shall strengthen the administration of clinical research initiating

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

institutions, cooperate with the health commissions in carrying out supervision and inspection involving new biomedical technologies, and promptly notify the health commission at the same level upon discovering violations of these Regulations.

Article 41 — The health commission of the State Council shall establish an online service system for the clinical research and clinical translational application of new biomedical technologies, providing convenience for clinical research initiating institutions and clinical research institutions in filing, applying for administrative licensing and reporting information. The health commissions of people's governments at or above the county level shall promptly publish supervision and administration information such as filing, administrative licensing, supervision and inspection, and investigation and punishment of illegal acts through the online service system.

The health commission of the State Council shall guide professional institutions in strengthening capacity building and improving the professional level of evaluation.

Article 42 — The health commissions of people's governments at or above the county level shall publish their email addresses and telephone numbers, accept complaints and reports, and handle them promptly. For reports verified to be true, the reporting person shall be rewarded in accordance with the relevant provisions of the State.

The health commissions of people's governments at or above the county level shall keep the information of reporting persons confidential and protect their lawful rights and interests.

Chapter VI — Legal Liability

Article 43 — Where clinical research is conducted on a new biomedical technology that is prohibited, or a new biomedical technology whose clinical research is prohibited is applied clinically, in violation of Article 9, paragraph 2 of these Regulations, the health commission of the people's government at or above the county level shall order cessation of the illegal act, confiscate the illegal gains and relevant materials and articles; where there are no illegal gains or the illegal gains are less than 1,000,000 yuan, a fine of not less than 1,000,000 yuan and not more than 10,000,000 yuan shall be imposed; where the illegal gains are 1,000,000 yuan or more, a fine of not less than 10 times and not more than 20 times the illegal gains shall be imposed; the party shall be prohibited from conducting clinical research of new biomedical technologies within five years, and the medical institution practice license may be revoked by the original practice registration department or cessation of practice activities may be ordered by the original filing department; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 100,000 yuan and not more than 200,000 yuan shall be imposed, they shall be prohibited from engaging in clinical research of new biomedical technologies for 10 years or for life, and the practice certificates of the relevant medical personnel shall be revoked by the original practice registration department.

Article 44 — Under any of the following circumstances, the health commission of the people's government at or above the county level shall order cessation of the illegal act, confiscate the illegal gains and relevant materials and articles; where there are no illegal gains or the illegal gains are less than 1,000,000 yuan, a fine of not less than 500,000 yuan and not more than 5,000,000 yuan shall be imposed; where the illegal gains are 1,000,000 yuan or more, a fine of not less than 5 times and not more than 10 times the illegal gains shall be imposed; the party shall be prohibited from conducting clinical research of new biomedical technologies within three years, and the medical institution practice license may be revoked by the original practice registration department or cessation of practice activities may be ordered by the original filing department; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 20,000 yuan and not more than 100,000 yuan shall be imposed, they shall be prohibited from engaging in clinical research of new biomedical technologies within five years, and the practice certificates of the relevant medical personnel shall be revoked by the original

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

practice registration department:

(1) conducting clinical research on a new biomedical technology that has not been proven safe and effective through non-clinical research;

(2) conducting clinical research of a new biomedical technology without passing academic review or ethical review; or

(3) applying clinically a new biomedical technology whose clinical translational application has not been approved.

Article 45 — Where clinical research of a new biomedical technology is conducted without conforming to Article 10, paragraph 1 or Article 11 of these Regulations, the health commission of the people's government at or above the county level shall order cessation of the clinical research, confiscate the illegal gains and relevant materials and articles, impose a fine of not less than 200,000 yuan and not more than 1,000,000 yuan, and prohibit the party from conducting clinical research of new biomedical technologies within two years; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 10,000 yuan and not more than 50,000 yuan shall be imposed, and they shall be prohibited from engaging in clinical research of new biomedical technologies within three years.

Where clinical research of a new biomedical technology is conducted without filing in accordance with these Regulations, the health commission of the people's government at or above the county level shall order filing within a prescribed time limit; where filing is not completed within the time limit, a penalty shall be imposed in accordance with the preceding paragraph.

Article 46 — Under any of the following circumstances, the health commission of the people's government at or above the county level shall order cessation of the clinical research of the new biomedical technology and impose a fine of not less than 100,000 yuan and not more than 500,000 yuan; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 10,000 yuan and not more than 30,000 yuan shall be imposed, they shall be prohibited from engaging in clinical research of new biomedical technologies within two years, and the relevant medical personnel shall be ordered to suspend practice for not less than six months and not more than one year, up to revocation of their practice certificates by the original practice registration department:

(1) the clinical research institution fails to suspend clinical research of the new biomedical technology or change the clinical research plan as required by the health commission of the State Council, or fails to terminate the clinical research as required by the health commission of the State Council;

(2) the clinical research institution implements clinical research of the new biomedical technology without obtaining written informed consent from the research subject or his or her guardian in accordance with Article 19 of these Regulations;

(3) the clinical research initiating institution or the clinical research institution forges, alters or conceals clinical research records or original materials of the new biomedical technology; or

(4) the clinical research institution fails to terminate clinical research of the new biomedical technology in accordance with Article 25 of these Regulations.

Article 47 — Under any of the following circumstances, the health commission of the people's government at or above the county level shall order rectification within a prescribed time limit and impose a fine of not less than 50,000 yuan and not more than 200,000 yuan, and may order suspension of the clinical research of the new biomedical technology; where the circumstances are serious, cessation of the clinical research shall be ordered and a fine of not less than 200,000 yuan and not more than 500,000 yuan shall be imposed; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 10,000 yuan and not more than 30,000 yuan shall be imposed, and

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

they shall be prohibited from engaging in clinical research of new biomedical technologies within two years:

(1) the clinical research institution fails to implement clinical research of the new biomedical technology in accordance with the filed clinical research plan, except where the change is a non-substantive change to the clinical research plan;

(2) the clinical research institution fails to take risk prevention, control and handling measures in accordance with Article 21, paragraph 1 of these Regulations;

(3) the clinical research institution arranges for personnel without the corresponding qualifications to carry out operations on the human body in violation of Article 21, paragraph 2 of these Regulations; or

(4) the clinical research institution fails to treat research subjects in accordance with Article 27, paragraph 1 of these Regulations, or commits other acts that harm the lawful rights and interests of research subjects.

Article 48 — Under any of the following circumstances, the health commission of the people's government at or above the county level shall order rectification within a prescribed time limit and may order suspension of the clinical research of the new biomedical technology; where the circumstances are serious, cessation of the clinical research shall be ordered, and the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law:

(1) the clinical research institution fails to record the implementation of clinical research or retain original materials in accordance with Article 22, paragraph 1 of these Regulations;

(2) the clinical research institution fails to inform the relevant matters in accordance with Article 23 of these Regulations; or

(3) the clinical research institution fails to report the implementation of clinical research in accordance with Article 24 of these Regulations.

Where the clinical research institution fails to report in accordance with Articles 25 and 26 of these Regulations, or a medical institution fails to report in accordance with Article 35 of these Regulations, the health commission of the people's government at or above the county level shall order rectification within a prescribed time limit; where rectification is not made within the time limit, a fine of not less than 20,000 yuan and not more than 50,000 yuan shall be imposed.

Article 49 — Where the clinical research initiating institution or the clinical research institution charges research subjects fees related to clinical research of the new biomedical technology, the market regulation department of the people's government at or above the county level shall order refund and impose a fine of not more than five times the illegally collected fees; where the circumstances are serious, suspension of business for rectification shall be ordered.

Article 50 — Where a medical institution that does not meet the conditions prescribed by the health commission of the State Council conducts clinical application of a new biomedical technology whose clinical translational application has been approved, the health commission of the people's government at or above the county level shall order cessation of the clinical application, confiscate the illegal gains, and impose a fine of not less than 100,000 yuan and not more than 500,000 yuan; where the circumstances are serious, a fine of not less than 500,000 yuan and not more than 1,000,000 yuan shall also be imposed.

Article 51 — Where the clinical research initiating institution provides false materials or adopts other fraudulent means when applying for a clinical translational application license for a new biomedical technology, the application shall not be accepted or no administrative license shall be granted; where an administrative license has already been obtained, the health commission of the State Council shall revoke the administrative license, confiscate the illegal gains, impose a fine of not less than 5 times and not more than 10 times the illegal gains, and prohibit the party from conducting clinical research of new biomedical technologies within three years; the responsible leading personnel and directly responsible personnel shall

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

be given sanctions in accordance with the law and a fine of not less than 20,000 yuan and not more than 100,000 yuan shall be imposed, and they shall be prohibited from engaging in clinical research of new biomedical technologies within five years.

Where the clinical research institution provides false materials or adopts other fraudulent means in the filing of clinical research of a new biomedical technology, the health commission of the State Council shall order cessation of the clinical research, confiscate the illegal gains and relevant materials and articles, impose a fine of not less than 2 times and not more than 5 times the illegal gains, and prohibit the party from conducting clinical research of new biomedical technologies within two years; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 10,000 yuan and not more than 50,000 yuan shall be imposed, and they shall be prohibited from engaging in clinical research of new biomedical technologies within three years.

Article 52 — Where a professional institution issues false evaluation opinions in evaluation, the health commission of the people's government at or above the county level shall impose a fine of not less than 100,000 yuan and not more than 500,000 yuan and prohibit it from participating in evaluation work related to new biomedical technologies within three years; the responsible leading personnel and directly responsible personnel shall be given sanctions in accordance with the law and a fine of not less than 10,000 yuan and not more than 50,000 yuan shall be imposed, and they shall be prohibited from participating in evaluation work related to new biomedical technologies within five years.

Article 53 — Where staff members of the health commissions and other departments violate these Regulations by abusing their authority, neglecting their duties or practicing favoritism, they shall be given sanctions in accordance with the law.

Article 54 — Where a violation of these Regulations causes personal or property damage, civil liability shall be borne in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Chapter VII — Supplementary Provisions

Article 55 — Clinical trials conducted for the development of drugs and medical devices shall be carried out in accordance with the provisions of laws and administrative regulations such as the Drug Administration Law of the People's Republic of China and the Regulations on the Supervision and Administration of Medical Devices.

The health commission of the State Council shall, in conjunction with the drug regulatory department of the State Council and based on the development of science and technology, formulate and adjust the guiding principles for the demarcation between new biomedical technologies and drugs and medical devices.

Article 56 — Clinical research and clinical translational application of new biomedical technologies conducted by military medical institutions shall be supervised and administered by the relevant departments of the organs of the Central Military Commission with reference to these Regulations.

Article 57 — For clinical research of new biomedical technologies already conducted before the implementation of these Regulations, the clinical research institution may continue its implementation in accordance with the clinical research plan and shall file in accordance with these Regulations within one month from the date of implementation of these Regulations.

Article 58 — These Regulations shall come into force as of May 1, 2026.

Source: https://www.danyoungcpa.com/new-biomedical-technologies-clinical-research-translational-application-regulations-china-2025/

Disclaimer: This document is an unofficial English translation of the original Chinese text, provided for reference purposes only. While every effort has been made to ensure accuracy, the Chinese-language version is the sole authoritative text. This translation does not constitute legal advice, and no liability is accepted for any reliance placed upon it. For matters with legal implications, please consult the official Chinese source and seek qualified professional advice.