生物医学新技术临床研究和临床转化应用管理条例

Regulation on the Administration of Clinical Research on and Clinical Translational Application of New Biomedical Technologies

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(No. 818)

The Regulation on the Administration of Clinical Research on and Clinical Translational Application of New Biomedical Technologies, as adopted at the 68th executive meeting of the State Council on September 12, 2025, is hereby issued with effect from May 1, 2026.

Li Qiang, Premier of the State Council

中华人民共和国国务院令

（第818号）

《生物医学新技术临床研究和临床转化应用管理条例》已经2025年9月12日国务院第68次常务会议通过，现予公布，自2026年5月1日起施行。

总理 李强

September 28, 2025

2025 年 9 月 28 日

Regulation on the Administration of Clinical Research on and Clinical Translational Application of New Biomedical Technologies

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Chapter I General Provisions

第一章　总　　则

Article 1 This Regulation is enacted for purposes of regulating clinical research on and clinical translational application of new biomedical technologies, advancing progress and innovation in medical science and technology, ensuring the quality and safety of medical treatment, and safeguarding human dignity and health.

第一条　为了规范生物医学新技术临床研究和临床转化应用，促进医学科学技术进步和创新，保障医疗质量安全，维护人的尊严和健康，制定本条例。

Article 2 This Regulation applies to clinical research, clinical translational application, and supervision and administration of new biomedical technologies conducted within the territory of the People's Republic of China.

第二条　在中华人民共和国境内从事生物医学新技术临床研究、临床转化应用及其监督管理，应当遵守本条例。

Article 3 For the purpose of this Regulation, the term "new biomedical technologies" means medical techniques and measures that are based on biological principles, function at the cellular or molecular level in humans, have not been clinically applied in China, and serve to assess health status, prevent or treat diseases, or promote health.

第三条　本条例所称生物医学新技术，是指以对健康状态作出判断或者预防治疗疾病、促进健康为目的，运用生物学原理，作用于人体细胞、分子水平，在我国境内尚未应用于临床的医学专业手段和措施。

Article 4 The conduct of clinical research on and clinical translational application of new biomedical technologies shall prioritize people's health, be guided by innovation, and maintain a proper balance between development and security.

第四条 开展生物医学新技术临床研究和临床转化应用应当坚持以人民健康为中心，坚持创新引领发展，坚持发展和安全并重。

The state adopts measures to promote the innovative development of new biomedical technologies, and encourages and supports clinical research on and clinical translational application thereof.

国家采取措施促进生物医学新技术创新发展，鼓励和支持生物医学新技术临床研究和临床转化应用。

Clinical research on and clinical translational application of new biomedical technologies shall be scientifically substantiated, comply with laws, administrative regulations, and relevant provisions issued by the state, and be subject to whole-process safety management controls, and shall not endanger human health, violate ethical principles, or harm public interests or national security.

开展生物医学新技术临床研究和临床转化应用应当具有科学依据，遵守法律、行政法规和国家有关规定，加强全过程安全管理，不得危害人体健康，不得违反伦理原则，不得损害公共利益和国家安全。

Article 5 Clinical research on new biomedical technologies shall respect subjects' voluntary will, safeguard subjects' dignity, and protect subjects' lawful rights and interests.

第五条 开展生物医学新技术临床研究应当尊重受试者意愿，维护受试者尊严，保护受试者合法权益。

Article 6 The health administration department of the State Council shall be responsible for the supervision and administration of clinical research on and clinical translational application of new biomedical technologies nationwide.

第六条 国务院卫生健康部门负责全国生物医学新技术临床研究和临床转化应用监督管理工作。

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 on and clinical translational application of new biomedical technologies within their respective administrative regions.

县级以上地方人民政府卫生健康部门负责本行政区域的生物医学新技术临床研究和临床转化应用监督管理工作。

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

县级以上人民政府其他有关部门在各自职责范围内负责与生物医学新技术临床研究和临床转化应用有关的监督管理工作。

Article 7 Entities and individuals that make outstanding contributions to clinical research on and clinical translational application of new biomedical technologies shall be commended or awarded in accordance with the relevant provisions issued by the state.

第七条 对在生物医学新技术临床研究和临床转化应用中做出突出贡献的单位和个人，按照国家有关规定给予表彰、奖励。

Chapter II Clinical Research Recordation

第二章 临床研究备案

Article 8 For the purposes of this Regulation, "clinical research on new biomedical technologies" means activities that involve conducting trials of new biomedical technologies through any of the following approaches to evaluate their safety and effectiveness and to define their scope of application, operating procedures, and technical specifications.

第八条 本条例所称生物医学新技术临床研究，是指以下列方式进行生物医学新技术试验，以判断其安全性、有效性，明确其适用范围、操作流程、技术要点等的活动：

(1) Performing direct operations on the human body.

（一）直接对人体进行操作的；

(2) Performing operations on isolated cells, tissues, or organs, followed by their implantation or transfusion into the human body.

（二）对离体的细胞、组织、器官等进行操作，后植入或者输入人体的；

(3) Performing operations on human germ cells, zygotes, or embryos, followed by implantation into the human body for development.

（三）对人的生殖细胞、合子、胚胎进行操作，后植入人体使其发育的；

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

（四）国务院卫生健康部门规定的其他方式。

Article 9 Before conducting clinical research on new biomedical technologies, non-clinical research such as laboratory research and animal experiments shall be carried out in accordance with the law. Clinical research may be conducted only after the safety and effectiveness of such technologies have been demonstrated through such non-clinical research.

第九条 开展生物医学新技术临床研究前，应当依法开展实验室研究、动物实验等非临床研究；经非临床研究证明该技术安全、有效的，方可开展临床研究。

An organization or individual may not conduct clinical research on new biomedical technologies that are expressly prohibited by laws, administrative regulations, or relevant provisions issued by the state, or that involve significant ethical issues.

对法律、行政法规和国家有关规定明令禁止的生物医学新技术，以及存在重大伦理问题的生物医学新技术，任何组织和个人不得开展临床研究。

Article 10 An institution sponsoring clinical research on new biomedical technologies (“clinical research sponsor”) shall be

第十条 发起生物医学新技术临床研究的机构（以下简称临

a legal person lawfully established within the territory of China.

床研究发起机构）应当是在我国境内依法成立的法人。

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

临床研究发起机构应当确保拟开展临床研究的生物医学新技术已经非临床研究证明安全、有效。

Article 11 An institution conducting clinical research on new biomedical technologies ("clinical research institution") shall meet the following conditions:

第十一条 实施生物医学新技术临床研究的机构（以下简称临床研究机构）应当具备下列条件:

(1) It shall be a Class A tertiary medical institution;

（一）是三级甲等医疗机构;

(2) It shall have an academic committee and an ethics committee for clinical research that meet the required standards;

（二）有符合要求的临床研究学术委员会和伦理委员会;

(3) It shall possess qualifications, premises, facilities, equipment, management bodies, professional personnel, and research capabilities commensurate with the intended clinical research on new biomedical technologies;

（三）有与拟开展的生物医学新技术临床研究相适应的资质、场所、设施、设备、管理机构、专业技术人员和研究能力;

(4) It shall have management systems ensuring research quality and safety, compliance with ethical principles, and protection of the lawful rights and interests of research subjects; and

（四）有保障临床研究质量安全、符合伦理原则以及保护受试者合法权益的管理制度;

(5) It shall have stable and sufficient funding sources for research.

（五）有稳定、充足的研究经费来源。

Article 12 The clinical research sponsor and the clinical research institution shall enter into a written agreement specifying their respective rights and obligations and jointly formulate a clinical research protocol.

第十二条 临床研究发起机构和临床研究机构应当签订书面协议，约定双方权利义务，并共同制定临床研究方案。

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

临床研究机构也可以自行发起生物医学新技术临床研究。

Article 13 A clinical research institution shall appoint a principal investigator for clinical research on new biomedical technologies. The principal investigator shall hold a practicing physician qualification and a senior professional title, demonstrate sound professional ethics, research credibility, and clinical expertise, possess the professional knowledge, experience, and capability required for conducting such clinical research, and maintain the clinical research institution as his or her primary practice institution.

第十三条 临床研究机构应当确定生物医学新技术临床研究项目负责人。项目负责人应当具备执业医师资格和高级职称，具有良好的职业道德、科学研究信誉和临床技术水平，具备承担生物医学新技术临床研究所需的专业知识、经验和能力，并以临床研究机构为主要执业机构。

Other personnel participating in clinical research on new biomedical technologies shall possess appropriate qualifications, professional knowledge, experience, and capability.

其他参与生物医学新技术临床研究的人员应当具备相应的资格、专业知识、经验和能力。

Article 14 Both the academic committee and the ethics

第十四条 临床研究机构的

committee of a clinical research institution shall conduct academic and ethical reviews of the proposed clinical research as required by applicable provisions. Clinical research may be conducted only after both the academic and ethical reviews have been approved.

临床研究学术委员会、伦理委员会应当按照规定对拟开展的生物医学新技术临床研究进行学术审查、伦理审查；通过学术审查、伦理审查的，方可开展临床研究。

Article 15 Within five working days from the date on which the clinical research on new biomedical technologies passes the academic and ethical reviews, the clinical research institution shall file for recordation with the health department of the State Council.

第十五条 临床研究机构应当自生物医学新技术临床研究通过学术审查、伦理审查之日起5个工作日内向国务院卫生健康部门备案。

Where a clinical research sponsor initiates the same clinical research project in two or more clinical research institutions, the primary clinical research institution designated by the sponsor shall file for recordation according to the preceding paragraph.

临床研究发起机构在两个以上临床研究机构发起同一项生物医学新技术临床研究的，由临床研究发起机构选择的主要临床研究机构依照前款规定备案。

Article 16 For the recordation of clinical research on new biomedical technologies, the following materials shall be submitted:

第十六条 进行生物医学新技术临床研究备案，应当提交下列资料：

(1) Basic information about the clinical research sponsor and clinical research institution;

（一）临床研究发起机构、临床研究机构的基本情况；

(2) Basic information about the researchers;

（二）研究人员的基本情况；

(3) The groundwork for the clinical research (including, among other things, summaries of scientific literature, and non-clinical research reports);

（三）临床研究工作基础（包括科学文献总结、非临床研究报告等）；

(4) The clinical research protocol;

（四）临床研究方案；

(5) Potential risks arising from the clinical research, as well as preventive and control measures and emergency response plans;

（五）临床研究可能产生的风险及其预防控制措施和应急处置预案；

(6) Academic review opinions and ethical review opinions;

（六）学术审查意见、伦理审查意见；

(7) The informed consent form (template);

（七）知情同意书（样式）；

(8) Proof of the sources of research funding and plans for the use thereof;

（八）研究经费来源证明和使用方案；

(9) Other materials as prescribed by the health department of the State Council.

（九）国务院卫生健康部门规定的其他资料。

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

临床研究机构应当确保提交的资料真实、准确、完整。

Article 17 The health department of the State Council shall make public information on clinical research on new

第十七条 国务院卫生健康

biomedical technologies that has been filed for recordation, including the clinical research sponsor, the clinical research institution, and other relevant particulars.

部门应当公布已备案的生物医学新技术临床研究及其临床研究发起机构、临床研究机构等信息。

The health department of the State Council shall, in accordance with applicable provisions, organize professional institutions to evaluate clinical research on new biomedical technologies that has been filed for recordation. Where, upon evaluation, technical or ethical risks are identified, the health department of the State Council may require the clinical research institution to suspend the clinical research or modify the clinical research protocol; where major technical or ethical risks are identified, it shall require the clinical research institution to terminate the clinical research.

国务院卫生健康部门按照规定组织专业机构对已备案的生物医学新技术临床研究进行评估。经评估，临床研究存在技术风险或者伦理风险的，国务院卫生健康部门可以要求临床研究机构暂停临床研究、变更临床研究方案；临床研究存在重大技术风险或者重大伦理风险的，国务院卫生健康部门应当要求临床研究机构终止临床研究。

Chapter III Implementation of Clinical Research

第三章　临床研究实施

Article 18 A clinical research institution shall conduct clinical research on new biomedical technologies in accordance with the clinical research protocol that has been filed for recordation. Where it is reasonably necessary to modify the clinical research protocol, the modification shall be reviewed and approved by both the academic committee and the ethics committee, and shall be filed for recordation with the health department of the State Council within five working days from the date on which it passes the academic and ethical reviews, except for non-substantive modifications that do not involve the research objectives, research methods,

第十八条　临床研究机构应当按照经备案的临床研究方案实施生物医学新技术临床研究。确需变更临床研究方案的，应当经临床研究学术委员会、伦理委员会审查通过，并自通过学术审查、伦理审查之日起5个工作日内向国务院卫生健康部门变更备案，但是不涉及研究目的、研究方法、主要研究终点、统计方

primary endpoints, statistical methods, or research subjects.

法、受试者等的非实质性变更除外。

Article 19 A clinical research institution shall obtain the written informed consent of the research subjects before conducting clinical research on new biomedical technologies. Where a research subject is a person with no capacity for civil conduct or limited capacity for civil conduct, written informed consent shall be lawfully obtained from his or her guardian.

第十九条 临床研究机构实施生物医学新技术临床研究，应当取得受试者的书面知情同意。受试者为无民事行为能力人或者限制民事行为能力人的，应当依法取得其监护人的书面知情同意。

A clinical research institution shall inform the research subjects or their guardians, in a manner easily understandable to them, of the purpose and protocol of the clinical research, disclose the potential risks involved, and inform them of the rights and interests to which they are entitled. A clinical research institution shall not obtain consent from the research subjects or their guardians by means of deception, coercion, or undue inducement.

临床研究机构应当以受试者或者其监护人容易理解的方式告知其临床研究的目的、方案，披露可能产生的风险，并告知受试者享有的权益。临床研究机构不得以欺骗、胁迫或者利诱方式取得受试者或者其监护人的同意。

Where a modification to the clinical research protocol may affect the rights and interests of the research subjects, the clinical research institution shall re-obtain the written informed consent from the research subjects or their guardians.

变更临床研究方案对受试者权益可能产生影响的，临床研究机构应当重新取得受试者或者其监护人的书面知情同意。

Article 20 The clinical research sponsor and the clinical research institution shall not charge the research subject any fees related to clinical research on new biomedical technologies.

第二十条 临床研究发起机构、临床研究机构不得向受试者收取与生物医学新技术临床研究

有关的费用。

Article 21 A clinical research institution shall take measures to prevent, control, and address risks arising in the implementation of clinical research on new biomedical technologies.

第二十一条 临床研究机构应当采取措施，预防控制和处置生物医学新技术临床研究实施中的风险。

In the course of clinical research on new biomedical technologies, any procedures performed on the research subjects shall be conducted by qualified healthcare professionals; medicinal products and medical devices used shall comply with the Medicinal Product Administration Law of the People's Republic of China, the Regulation on the Supervision and Administration of Medical Devices, and other relevant laws and administrative regulations.

生物医学新技术临床研究过程中，作用于人体的操作应当由具备相应资格的卫生专业技术人员实施；使用的药品、医疗器械应当符合《中华人民共和国药品管理法》、《医疗器械监督管理条例》等法律、行政法规规定。

Article 22 A clinical research institution shall promptly, accurately, and completely record the implementation of clinical research on new biomedical technologies, and retain relevant original materials. Such records and original materials shall be retained for 30 years from the date of completion of the clinical research; where the clinical research involves offspring, the records and original materials shall be permanently retained.

第二十二条 临床研究机构应当及时、准确、完整记录生物医学新技术临床研究实施情况，留存相关原始材料。记录和原始材料应当自临床研究结束起保存30年；临床研究涉及子代的，记录和原始材料应当永久保存。

The clinical research sponsor and the clinical research institution shall not fabricate, alter, or conceal any records or original materials related to the clinical research on new biomedical technologies.

临床研究发起机构、临床研究机构不得伪造、篡改、隐匿生物医学新技术临床研究记录和原始材料。

Article 23 Where a clinical research institution requires another institution to provide technical support in the implementation of clinical research on new biomedical technologies, provide biological samples such as human cells, tissues, or organs, or assist in the recruitment of research subjects, it shall inform the other institution of the objectives and protocol of the clinical research, its recordation status, and the intended use of the biological samples.

第二十三条 临床研究机构需要其他机构为其实施生物医学新技术临床研究提供技术支持，提供人体细胞、组织、器官等生物样本，或者协助招募受试者的，应当告知临床研究的目的、方案、备案情况和生物样本的用途。

Article 24 A clinical research institution shall periodically report the implementation of clinical research on new biomedical technologies to the health department of the State Council.

第二十四条 临床研究机构应当定期向国务院卫生健康部门报告生物医学新技术临床研究实施情况。

Article 25 Where any of the following circumstances occurs, the clinical research institution shall terminate the clinical research on new biomedical technologies, report to the health department of the State Council within five working days, and notify the clinical research sponsor:

第二十五条 有下列情形之一的，临床研究机构应当终止生物医学新技术临床研究，于5个工作日内向国务院卫生健康部门报告，并告知临床研究发起机构：

(1) Major issues concerning the safety or efficacy of new biomedical technologies are discovered.

（一）发现生物医学新技术的安全性、有效性存在重大问题；

(2) The clinical research causes or is likely to cause major adverse social impacts.

（二）临床研究产生或者可能产生重大社会不良影响；

(3) Uncontrollable risks arise during the clinical research.

（三）临床研究过程中出现不可控制的风险；

(4) Other circumstances specified by the health department of the State Council.

（四）国务院卫生健康部门规定的其他情形。

Where severe adverse reactions occur during clinical research on new biomedical technologies, the clinical research institution shall suspend the clinical research, and the ethics committee of the clinical research shall evaluate whether continuation is feasible. The clinical research institution shall, based on the evaluation opinion, terminate or resume the research, report to the health department of the State Council within five working days, and notify the clinical research sponsor.

生物医学新技术临床研究过程中发生严重不良反应的，临床研究机构应当暂停临床研究，由临床研究伦理委员会就是否可以继续实施临床研究进行评估。临床研究机构应当根据评估意见终止临床研究或者继续实施临床研究，于5个工作日内向国务院卫生健康部门报告，并告知临床研究发起机构。

Article 26 After the completion of clinical research on new biomedical technologies, the clinical research institution shall report the implementation status, research outcomes, and recommendations on clinical translational application to the health department of the State Council. The clinical research institution shall conduct follow-up monitoring of subjects to evaluate the long-term safety and effectiveness of the new biomedical technologies.

第二十六条 生物医学新技术临床研究结束后，临床研究机构应当向国务院卫生健康部门报告临床研究实施情况、研究结果和临床转化应用建议。临床研究机构应当对受试者进行随访监测，评价生物医学新技术的长期安全性、有效性。

Article 27 Where clinical research on new biomedical technologies causes harm to the health of the research

第二十七条 生物医学新技术临床研究造成受试者健康损害

subjects, the clinical research institution shall provide timely treatment, and the treatment costs shall be borne by the clinical research sponsor. However, where the harm to the health of the research subjects results from the fault of the clinical research institution, the treatment costs shall be borne by the clinical research institution.

的，临床研究机构应当及时予以治疗，治疗费用由临床研究发起机构承担；但是，因临床研究机构过错造成受试者健康损害的，治疗费用由临床研究机构承担。

The clinical research sponsor and the clinical research institution shall be encouraged to provide corresponding protection for the research subjects by purchasing commercial insurance.

鼓励临床研究发起机构、临床研究机构通过购买商业保险为受试者提供相应的保障。

Article 28 The clinical research sponsor, the clinical research institution, and other institutions involved in the clinical research on new biomedical technologies shall, in accordance with the law, protect the personal privacy and personal information of the research subjects.

第二十八条 临床研究发起机构、临床研究机构以及其他与生物医学新技术临床研究有关的机构应当依法保护受试者的个人隐私、个人信息。

Chapter IV Clinical Translational Application

第四章 临床转化应用

Article 29 Where a new biomedical technology, upon completion of clinical research, is intended for clinical translational application, it shall be subject to review and approval by the health department of the State Council.

第二十九条 生物医学新技术临床研究结束后拟转化应用于临床的，应当经国务院卫生健康部门审查批准。

Article 30 Where a new biomedical technology is intended for clinical translational application, the clinical research sponsor shall submit an application to the health department of the State Council and provide the following materials:

第三十条 生物医学新技术拟转化应用于临床的，临床研究发起机构应当向国务院卫生健康

部门提出申请，并提交下列资料：

(1) Clinical research reports and records of the new biomedical technology.

（一）生物医学新技术临床研究报告和记录；

(2) The applicable scope, potential adverse reactions, and contraindications of the new biomedical technology.

（二）生物医学新技术的适用范围、可能出现的不良反应和禁忌；

(3) The qualifications required for medical institutions and healthcare professionals applying the new biomedical technology.

（三）应用生物医学新技术的医疗机构、卫生专业技术人员需要具备的条件；

(4) Clinical operational procedures.

（四）临床应用操作规范；

(5) The potential risks involved in clinical application and corresponding prevention and control measures.

（五）临床应用中可能产生的风险及其预防控制措施；

(6) Other materials as required by the health department of the State Council.

（六）国务院卫生健康部门规定的其他资料。

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

临床研究发起机构应当确保提交的资料真实、准确、完整。

Article 31 The health department of the State Council shall, within five working days from the date of accepting an

第三十一条 国务院卫生健

application for the clinical translational application of a new biomedical technology, forward the application materials to the professional institutions for technical and ethical evaluations, and shall, within fifteen working days from the date of receiving the evaluation opinions, make a decision. Approval shall be granted if the clinical research demonstrates that the technology is safe, effective, and consistent with ethical principles; otherwise, approval shall be denied with written reasons given.

康部门应当自受理生物医学新技术临床转化应用申请之日起5个工作日内将申请资料转交专业机构进行技术评估、伦理评估，并自收到评估意见之日起15个工作日内作出决定。对临床研究证明安全、有效，且符合伦理原则的，予以批准；对不符合上述要求的，不予批准，并书面说明理由。

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

生物医学新技术临床转化应用申请审查工作规范以及技术评估、伦理评估工作规则，由国务院卫生健康部门制定。

Article 32 Applications for the clinical translational application of new biomedical technologies that are used to treat life-threatening diseases with no effective treatment methods or are urgently needed for public health purposes shall be subject to prioritized review and approval by the health department of the State Council.

第三十二条 对治疗严重危及生命且尚无有效治疗手段的疾病以及公共卫生方面急需的生物医学新技术的临床转化应用申请，国务院卫生健康部门应当予以优先审查审批。

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 requirements for medical institutions and healthcare professionals applying such technology, and the

第三十三条 国务院卫生健康部门批准生物医学新技术临床转化应用的，应当公布技术名称、应用该技术的医疗机构和卫生专业技术人员应当具备的条件

operational standards for clinical application.

以及临床应用操作规范。

Article 34 A medical institution conducting the clinical application of an approved new biomedical technology shall meet the conditions prescribed by the health department of the State Council. The medical institution and its medical personnel shall comply with the operational standards for clinical application of the technology, ensure the quality and safety of medical treatment, and prevent and control risks. The medical institution may charge fees in accordance with applicable provisions.

第三十四条 对经批准临床转化应用的生物医学新技术，医疗机构开展临床应用的，应当具备国务院卫生健康部门规定的条件。医疗机构及其医务人员应当遵守该技术的临床应用操作规范，保障医疗质量安全，预防控制风险。医疗机构开展临床应用可以按照规定收取费用。

Article 35 A medical institution shall report to the health department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located, on the clinical application of the approved new biomedical technology, in accordance with the provisions issued by the health department of the State Council. Where a serious adverse reaction or medical accident occurs during clinical application, the medical institution shall handle it in accordance with applicable provisions.

第三十五条 医疗机构应当按照国务院卫生健康部门的规定向所在地省、自治区、直辖市人民政府卫生健康部门报告经批准临床转化应用的生物医学新技术临床应用情况。临床应用过程中发生严重不良反应或者医疗事故的，医疗机构应当按照规定进行处理。

Article 36 To respond to a particularly serious public health emergency or any other emergency seriously threatening public health, the health department of the State Council may approve the emergency application, within a specified scope and duration, of a new biomedical technology undergoing clinical research, upon an expert demonstration confirming the necessity of such emergency application.

第三十六条 为应对特别重大突发公共卫生事件或者其他严重威胁公众健康的紧急事件，国务院卫生健康部门经组织论证确有必要的，可以同意在一定范围和期限内紧急应用正在开展临床

研究的生物医学新技术。

Article 37 Where a new biomedical technology approved for clinical translational application falls under any of the following circumstances, the health department of the State Council shall reassess its safety and effectiveness, and the clinical application of the technology shall be suspended during the reassessment period:

第三十七条 经批准临床转化应用的生物医学新技术有下列情形之一的，国务院卫生健康部门应当对其安全性、有效性进行再评估，再评估期间暂停临床应用该技术：

(1) Scientific developments have led to a change in the understanding of the safety or effectiveness of the technology.

（一）根据科学研究的发展，对该技术的安全性、有效性有认识上的改变；

(2) A serious adverse reaction or an uncontrollable risk occurs during the clinical application.

（二）临床应用过程中发生严重不良反应或者出现不可控制的风险；

(3) Any other circumstance specified by the health department of the State Council.

（三）国务院卫生健康部门规定的其他情形。

Where the reassessment concludes that the safety or effectiveness cannot be ensured, the health department of the State Council shall prohibit the clinical application of the technology.

经评估不能保证安全、有效的，国务院卫生健康部门应当决定禁止临床应用该技术。

Chapter V Supervision and Administration

第五章 监督管理

Article 38 The health departments of people's governments at or above the county level shall carry out supervision and inspection over the clinical research on, and clinical translational application of, new biomedical technologies; where any act in violation of this Regulation is found, such departments shall handle it according to the law.

第三十八条 县级以上人民政府卫生健康部门应当对生物医学新技术临床研究和临床转化应用进行监督检查；发现违反本条例规定行为的，应当依法处理。

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

第三十九条 县级以上人民政府卫生健康部门进行监督检查时，可以采取下列措施：

(1) Entering the sites of clinical research or clinical application of new biomedical technologies to conduct on-site inspection.

（一）进入生物医学新技术临床研究或者临床应用场所实施现场检查；

(2) Reviewing and duplicating relevant records, medical records, agreements, invoices, account books, and other materials.

（二）查阅、复制有关记录、病历、协议、票据、账簿等资料；

(3) Sealing up or seizing equipment, medicinal products, medical devices, and other articles suspected of being illegally used for the clinical research or clinical application of new biomedical technologies.

（三）查封、扣押涉嫌用于违法开展生物医学新技术临床研究或者临床应用的设备、药品、医疗器械等物品；

(4) Sealing up sites or facilities suspected of being illegally used for the clinical research or clinical application of new biomedical technologies.

（四）查封涉嫌违法开展生物医学新技术临床研究或者临床应用的场所、设施。

The entities under inspection shall cooperate with the supervision and inspection, and shall not refuse or conceal any relevant information.

被检查单位对监督检查应当予以配合，不得拒绝、隐瞒。

Article 40 The competent authorities of clinical research sponsors, including scientific research institutions and educational institutions, shall strengthen the administration of clinical research sponsors, cooperate with health departments in conducting supervision and inspection concerning new biomedical technologies, and shall promptly report to the health departments at the same level any act in violation of the provisions of this Regulation.

第四十条 科研机构、教育机构等临床研究发起机构的主管部门应当加强对临床研究发起机构的管理，配合卫生健康部门开展涉及生物医学新技术的监督检查，发现违反本条例规定行为的，应当及时通报同级卫生健康部门。

Article 41 The health department of the State Council shall establish an online service system for the clinical research on and clinical translational application of new biomedical technologies, so as to facilitate recordation, application for administrative licensing, and information reporting by clinical research sponsors and clinical research institutions. The health departments of people's governments at or above the county level shall, through the online service system, promptly make public supervision and administration information, including information about recordation, administrative licensing, supervision and inspection, and investigation and handling of violations.

第四十一条 国务院卫生健康部门建立生物医学新技术临床研究和临床转化应用在线服务系统，为临床研究发起机构、临床研究机构等进行备案、申请行政许可、报告信息等提供便利。县级以上人民政府卫生健康部门应当通过在线服务系统及时公布备案、行政许可、监督检查、违法行为查处等监督管理信息。

The health department of the State Council shall guide professional institutions in strengthening capacity building to enhance the specialization of evaluation.

国务院卫生健康部门指导专业机构加强能力建设，提高评估的专业化水平。

Article 42 The health departments of people's governments at or above the county level shall make public their email addresses and telephone numbers for receiving complaints and reports, and shall handle such complaints and reports in a timely manner. Where a report is verified to be true, the whistleblower shall be given a reward in accordance with the relevant provisions issued by the state.

第四十二条 县级以上人民政府卫生健康部门应当公布本部门的电子邮件地址、电话，接受投诉、举报，并及时处理。对查证属实的举报，按照国家有关规定给予举报人奖励。

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

县级以上人民政府卫生健康部门应当对举报人的信息予以保密，保护举报人的合法权益。

CHAPTER VI LEGAL LIABILITY

第六章 法律责任

Article 43 Where a medical institution, in violation of paragraph 2 of Article 9 of this Regulation, conducts clinical research on prohibited new biomedical technologies or applies such prohibited biomedical technologies in clinical treatment, the health department of the people's government at or above the county level shall order the cessation of the illegal acts, confiscate the illegal gains and relevant materials and articles, and impose the following penalties: where there are no illegal gains or the illegal gains are less than 1 million yuan, a fine of not less than 1 million yuan nor more than 10 million yuan shall be imposed; where the illegal gains amount to 1 million yuan or more, a fine of not less than 10 times nor more than 20 times the amount of the illegal gains shall be imposed. The medical institution shall be prohibited from conducting clinical research on new biomedical technologies for five years, and the original licensing authority may revoke its practice license or the original

第四十三条 违反本条例第九条第二款规定，开展禁止开展的生物医学新技术临床研究，或者将上述禁止开展临床研究的生物医学新技术应用于临床的，由县级以上人民政府卫生健康部门责令停止违法行为，没收违法所得和有关资料、物品，没有违法所得或者违法所得不足100万元的，处100万元以上1000万元以下罚款，违法所得100万元以上的，处违法所得10倍以上20倍以下罚款，5年内禁止其开展生物医学新技术临床研究，并可以由原执业登记部门吊销医疗机构执

recordation authority may order cessation of its practice activities. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 100,000 yuan nor more than 200,000 yuan, and a prohibition, for 10 years or for life, from engaging in clinical research on new biomedical technologies, and the practice certificates of relevant medical personnel shall be revoked by the original registration authority.

业许可证或者由原备案部门责令停止执业活动；对负有责任的领导人员和直接责任人员，依法给予处分，处10万元以上20万元以下罚款，10年直至终身禁止其从事生物医学新技术临床研究，并由原执业注册部门吊销有关医务人员的执业证书。

Article 44 Where any of the following circumstances occurs to a medical institution, the health department of the people's government at or above the county level shall order the cessation of the illegal acts, confiscate the illegal gains and relevant materials and articles, and impose the following penalties: where there are no illegal gains or the illegal gains are less than 1 million yuan, a fine of not less than 500,000 yuan nor more than 5 million yuan shall be imposed; where the illegal gains amount to 1 million yuan or more, a fine of not less than 10 times nor more than 20 times the amount of the illegal gains shall be imposed. The medical institution shall be prohibited from conducting clinical research on new biomedical technologies for three years, and the original licensing authority may revoke its practice license or the original recordation authority may order cessation of its practice activities. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 20,000 yuan nor more than 100,000 yuan, and a prohibition, for five years or for life, from engaging in clinical research on new biomedical technologies, and the practice certificates of relevant medical personnel shall be revoked by the original registration

第四十四条 有下列情形之一的，由县级以上人民政府卫生健康部门责令停止违法行为，没收违法所得和有关资料、物品，没有违法所得或者违法所得不足100万元的，处50万元以上500万元以下罚款，违法所得100万元以上的，处违法所得5倍以上10倍以下罚款，3年内禁止其开展生物医学新技术临床研究，并可以由原执业登记部门吊销医疗机构执业许可证或者由原备案部门责令停止执业活动；对负有责任的领导人员和直接责任人员，依法给予处分，处2万元以上10万元以下罚款，5年内禁止其从事生物医学新技术临床研究，并由原执业注册部门吊销有关医务人员的执业证书：

authority:

(1) Conducting clinical research on new biomedical technologies that have not been demonstrated, by non-clinical studies, to be safe and effective.

（一）对未经非临床研究证明安全、有效的生物医学新技术开展临床研究；

(2) Conducting clinical research on new biomedical technologies that have not passed academic review or ethical review.

（二）未通过学术审查、伦理审查，开展生物医学新技术临床研究；

(3) Clinically applying biomedical technologies that have not obtained approval for clinical translational application.

（三）将未经批准临床转化应用的生物医学新技术应用于临床。

Article 45 Where a medical institution conducts clinical research on new biomedical technologies in violation of paragraph 1 of Article 10 or Article 11 of this Regulation, the health department 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 nor more than 1 million yuan, and prohibit the medical institution from conducting clinical research on new biomedical technologies for two years. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 10,000 yuan nor more than 50,000 yuan, and a three-year prohibition from engaging in clinical research on new biomedical technologies.

第四十五条 不符合本条例第十条第一款、第十一条规定开展生物医学新技术临床研究的，由县级以上人民政府卫生健康部门责令停止临床研究，没收违法所得和有关资料、物品，处20万元以上100万元以下罚款，2年内禁止其开展生物医学新技术临床研究；对负有责任的领导人员和直接责任人员，依法给予处分，处1万元以上5万元以下罚款，3年内禁止其从事生物医学新技术临床研究。

Where a medical institution that conducts clinical research on new biomedical technologies fails to undergo recordation as required by this Regulation, the health department of the people's government at or above the county level shall order it to file for recordation within a prescribed time limit; in case of failure to do so, it shall be penalized in accordance with the provisions of the preceding paragraph.

开展生物医学新技术临床研究未依照本条例规定备案的，由县级以上人民政府卫生健康部门责令限期备案；逾期未备案的，依照前款规定予以处罚。

Article 46 Where any of the following circumstances occurs, the health department of the people's government at or above the county level shall order cessation of clinical research on new biomedical technologies and impose a fine of not less than 100,000 yuan nor more than 500,000 yuan. Responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 10,000 yuan nor more than 30,000 yuan, and a two-year prohibition from engaging in clinical research on new biomedical technologies, and relevant medical personnel shall be ordered to suspend their practice activities for not less than six months nor more than one year, and their practice certificates shall be revoked by the original practice registration authority:

第四十六条 有下列情形之一的，由县级以上人民政府卫生健康部门责令停止生物医学新技术临床研究，处10万元以上50万元以下罚款；对负有责任的领导人员和直接责任人员，依法给予处分，处1万元以上3万元以下罚款，2年内禁止其从事生物医学新技术临床研究，并对有关医务人员责令暂停6个月以上1年以下执业活动直至由原执业注册部门吊销执业证书：

(1) A clinical research institution fails to suspend clinical research on new biomedical technologies or modify clinical research protocols as required by the health department of the State Council, or fails to terminate clinical research as required by the health department of the State Council.

（一）临床研究机构未按照国务院卫生健康部门的要求暂停生物医学新技术临床研究、变更临床研究方案，或者未按照国务院卫生健康部门的要求终止临床研究；

(2) A clinical research institution conducts clinical research on new biomedical technologies without obtaining written informed consent from subjects or their guardians as prescribed in Article 19 of this Regulation.

（二）临床研究机构未依照本条例第十九条规定取得受试者或者其监护人书面知情同意实施生物医学新技术临床研究；

(3) A clinical research sponsor or a clinical research institution falsifies, alters, or conceals clinical research records or original materials related to new biomedical technologies.

（三）临床研究发起机构、临床研究机构伪造、篡改、隐匿生物医学新技术临床研究记录、原始材料；

(4) A clinical research institution fails to terminate clinical research on new biomedical technologies as required by Article 25 of this Regulation.

（四）临床研究机构未依照本条例第二十五条规定终止生物医学新技术临床研究。

Article 47 Where any of the following circumstances occurs, the health department of the people's government at or above the county level shall order corrections to be made within a specified time limit, impose a fine of not less than 50,000 yuan nor more than 200,000 yuan, and may order suspension of clinical research on new biomedical technologies; if the circumstances are serious, it shall order termination of clinical research and impose a fine of not less than 200,000 yuan nor more than 500,000 yuan. Responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 10,000 yuan nor more than 30,000 yuan, and a two-year prohibition from engaging in clinical research on new biomedical technologies:

第四十七条 有下列情形之一的，由县级以上人民政府卫生健康部门责令限期改正，处5万元以上20万元以下罚款，并可以责令暂停生物医学新技术临床研究；情节严重的，责令停止临床研究，处20万元以上50万元以下罚款，对负有责任的领导人员和直接责任人员，依法给予处分，处1万元以上3万元以下罚款，2年内禁止其从事生物医学新技术临床研究：

(1) A clinical research institution fails to conduct clinical research on new biomedical technologies in accordance with the clinical research protocol that has been filed for recordation, except where such modifications are non-substantive.

（一）临床研究机构未按照经备案的临床研究方案实施生物医学新技术临床研究，但是属于临床研究方案非实质性变更的除外；

(2) A clinical research institution fails to take risk prevention, control, or disposition measures in accordance with paragraph 1 of Article 21 of this Regulation.

（二）临床研究机构未依照本条例第二十一条第一款规定采取风险预防控制、处置措施；

(3) A clinical research institution, in violation of paragraph 2 of Article 21 of this Regulation, assigns persons unqualified to perform operations on the human body.

（三）临床研究机构违反本条例第二十一条第二款规定，安排不具备相应资格的人员实施作用于人体的操作；

(4) A clinical research institution fails to provide treatment to subjects in accordance with paragraph 1 of Article 27 of this Regulation, or commits other acts that infringe upon the lawful rights and interests of subjects.

（四）临床研究机构未依照本条例第二十七条第一款规定对受试者进行治疗，或者有其他损害受试者合法权益的行为。

Article 48 Where any of the following circumstances occurs, the health department of the people's government at or above the county level shall order corrections to be made within a specified time limit, and may order suspension of clinical research on new biomedical technologies; if the circumstances are serious, it shall order termination of clinical research and impose disciplinary action on responsible leaders and directly liable persons in accordance with the law:

第四十八条 有下列情形之一的，由县级以上人民政府卫生健康部门责令限期改正，并可以责令暂停生物医学新技术临床研究；情节严重的，责令停止临床研究，对负有责任的领导人员和直接责任人员，依法给予处分：

(1) A clinical research institution fails to record the implementation of clinical research and retain the original materials in accordance with paragraph 1 of Article 22 of this Regulation.

（一）临床研究机构未依照本条例第二十二条第一款规定记录临床研究实施情况、留存原始材料；

(2) A clinical research institution fails to notify relevant matters in accordance with Article 23 of this Regulation.

（二）临床研究机构未依照本条例第二十三条规定告知有关事项；

(3) A clinical research institution fails to report the implementation of clinical research in accordance with Article 24 of this Regulation.

（三）临床研究机构未依照本条例第二十四条规定报告临床研究实施情况。

Where a clinical research institution fails to report in accordance with Article 25 or 26 of this Regulation, or a medical institution fails to report in accordance with Article 35 of this Regulation, the health department of the people's government at or above the county level shall order corrections to be made within a specified time limit; if no corrections are made within the prescribed time limit, a fine of not less than 20,000 yuan nor more than 50,000 yuan shall be imposed.

临床研究机构未依照本条例第二十五条、第二十六条规定报告，或者医疗机构未依照本条例第三十五条规定报告的，由县级以上人民政府卫生健康部门责令限期改正；逾期未改正的，处2万元以上5万元以下罚款。

Article 49 Where a clinical research sponsor or a clinical research institution collects fees related to clinical research on new biomedical technologies from subjects, the market regulation department of the people's government at or above the county level shall order such fees to be refunded

第四十九条 临床研究发起机构、临床研究机构向受试者收取与生物医学新技术临床研究有关的费用的，由县级以上人民政府市场监督管理部门责令退还，

and impose a fine of not more than five times the amount illegally collected; if the circumstances are serious, it shall order suspension of business for rectification.

处违法收取的费用5倍以下罚款；情节严重的，责令停业整顿。

Article 50 Where a medical institution that does not meet the conditions specified by the health department of the State Council conducts the clinical application of new biomedical technologies approved for clinical translational application, the health department of the people's government at or above the county level shall order termination of the clinical application, confiscate the illegal gains, and impose a fine of not less than 100,000 yuan nor more than 500,000 yuan; if the circumstances are serious, it shall impose a fine of not less than 500,000 yuan nor more than 1,000,000 yuan.

第五十条 不具备国务院卫生健康部门规定条件的医疗机构开展经批准临床转化应用的生物医学新技术临床应用的，由县级以上人民政府卫生健康部门责令停止临床应用，没收违法所得，并处10万元以上50万元以下罚款；情节严重的，并处50万元以上100万元以下罚款。

Article 51 Where a clinical research sponsor provides false materials or adopts other fraudulent means when applying for an administrative license for the clinical translational application of new biomedical technologies, the application shall not be accepted, or the administrative license shall not be granted; where the administrative license has been obtained, it shall be revoked by the health department of the State Council, the illegal gains shall be confiscated, and a fine of not less than five times nor more than ten times the amount of the illegal gains shall be imposed. The sponsor shall be prohibited, for three years, from conducting clinical research on new biomedical technologies. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 20,000 yuan nor more than 100,000 yuan, and a five-year prohibition from engaging in clinical research on

第五十一条 临床研究发起机构申请生物医学新技术临床转化应用许可时提供虚假资料或者采用其他欺骗手段的，不予受理或者不予行政许可，已经取得行政许可的，由国务院卫生健康部门撤销行政许可，没收违法所得，处违法所得5倍以上10倍以下罚款，3年内禁止其开展生物医学新技术临床研究；对负有责任的领导人员和直接责任人员，依法给予处分，处2万元以上10万元以下罚款，5年内禁止其从事生物医学新技术临床研究。

new biomedical technologies.

Where a clinical research institution provides false materials or adopts other fraudulent means when filing for recordation clinical research on new biomedical technologies, the health department of the State Council shall order it to cease the clinical research, confiscate the illegal gains and relevant materials and articles, impose a fine of not less than twice nor more than five times the amount of the illegal gains, and prohibit the institution, for two years, from conducting clinical research on new biomedical technologies. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 10,000 yuan nor more than 50,000 yuan, and a three-year prohibition from engaging in clinical research on new biomedical technologies.

临床研究机构在生物医学新技术临床研究备案中提供虚假资料或者采用其他欺骗手段的，由国务院卫生健康部门责令停止临床研究，没收违法所得和有关资料、物品，处违法所得2倍以上5倍以下罚款，2年内禁止其开展生物医学新技术临床研究；对负有责任的领导人员和直接责任人员，依法给予处分，处1万元以上5万元以下罚款，3年内禁止其从事生物医学新技术临床研究。

Article 52 Where a professional institution issues false assessment opinions, the health department of the people's government at or above the county level shall impose a fine of not less than 100,000 yuan nor more than 500,000 yuan, and shall prohibit it, for three years, from participating in assessment work related to new biomedical technologies. Its responsible leaders and directly liable persons shall be subject to disciplinary action in accordance with the law, a fine of not less than 10,000 yuan nor more than 50,000 yuan, and a five-year prohibition from participating in assessment work related to new biomedical technologies.

第五十二条 专业机构在评估中出具虚假评估意见的，由县级以上人民政府卫生健康部门处10万元以上50万元以下罚款，3年内禁止其参与生物医学新技术相关评估工作；对负有责任的领导人员和直接责任人员，依法给予处分，处1万元以上5万元以下罚款，5年内禁止其参与生物医学新技术相关评估工作。

Article 53 Any staff member of the health department or other relevant departments who, in violation of the provisions

第五十三条 卫生健康等部门工作人员违反本条例规定，滥

of this Regulation, abuses power, neglects duty, or engages in malpractices for personal gain shall be subject to disciplinary action in accordance with the law.

用职权、玩忽职守、徇私舞弊的，依法给予处分。

Article 54 Any person who causes personal injury or property damage in violation of the provisions of this Regulation shall be subject to civil liability in accordance with the law; where such violation constitutes a crime, the person shall be held criminally liable in accordance with the law.

第五十四条 违反本条例规定，造成人身、财产损害的，依法承担民事责任；构成犯罪的，依法追究刑事责任。

Chapter VII Supplemental Provisions

第七章 附 则

Article 55 Clinical trials conducted for purposes of developing medicinal products or medical devices shall be governed by the Medicinal Product Administration Law of the People's Republic of China, the Regulation on the Supervision and Administration of Medical Devices, and other laws and administrative regulations.

第五十五条 为研制药品、医疗器械开展临床试验的，依照《中华人民共和国药品管理法》、《医疗器械监督管理条例》等法律、行政法规规定执行。

The health department of the State Council shall, in conjunction with the drug regulatory department of the State Council, formulate and adjust, in light of scientific and technological developments, guiding principles for distinguishing new biomedical technologies from drugs and medical devices.

国务院卫生健康部门会同国务院药品监督管理部门根据科学技术的发展，制定、调整生物医学新技术与药品、医疗器械的界定指导原则。

Article 56 The clinical research on and clinical translational application of new biomedical technologies conducted by military medical institutions shall be supervised and

第五十六条 军队医疗机构开展生物医学新技术临床研究和临床转化应用，由中央军委机关

administered by relevant departments of the Central Military Commission authorities, mutatis mutandis, in accordance with the provisions of this Regulation.

有关部门参照本条例规定进行监督管理。

Article 57 Where clinical research on new biomedical technologies is conducted before the entry into force of this Regulation, the clinical research institution may continue such research in accordance with the research protocol, and shall, within one month from the date of its entry into force, file for recordation in accordance with the provisions of this Regulation.

第五十七条 本条例施行前已经开展的生物医学新技术临床研究，临床研究机构可以按照临床研究方案继续实施，并应当自本条例施行之日起1个月内依照本条例规定进行备案。

Article 58 This Regulation takes effect on May 1, 2026.

第五十八条 本条例自2026年5月1日起施行。