

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

China – State Council

Main information

Scope of Application:

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.

Effective Date:

May 1st, 2026

Related Provisions:

- Drug Administration Law
- Regulations on the Supervision and Administration of Medical Devices

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Key Topics

Framework

- **Three-tier risk-based classification system** for biomedical new technologies: High-risk technologies (e.g., germline gene editing, reproductive cloning) are either completely prohibited or require explicit State Council-level approval, while medium-to-low risk technologies (e.g., somatic cell therapy, certain tissue engineering products) are managed by provincial health authorities with stricter institutional review board oversight.
- **End-to-End Lifecycle Governance:** research protocol submission, patient informed consent, adverse event reporting, annual progress reviews, post-market surveillance, and mandatory outcomes disclosure in a national registry. No technology is exempt from post-approval monitoring, regardless of its initial risk classification.

What's new

- **Binding Definition of "Biomedical New Technology":** *“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”.*
- **Prohibition on Direct-to-Consumer Commercialization:** The regulation explicitly prohibits any institution or individual from advertising, marketing, or offering biomedical new technologies directly to consumers before receiving full clinical application approval. **Criminal liabilities** are established.
- **Mandatory Data Sharing with National Registry:** All clinical research data, including negative results and adverse events, must be uploaded to a centralized, publicly accessible National Biomedical New Technology Registry within 90 days of study completion.

Sensitive Factors

- **Patient Consent Invalid if not updated:** the consent shall be obtained at multiple timepoints: before screening, before intervention, and after any significant change in risk profile. Consent signed at enrollment is automatically voided if new safety information emerges during the study, and researchers must re-consent subjects. Failure to do so renders the entire study invalid for regulatory submission purposes.

Drivers

- **Regulatory Certainty for Venture Capital/Investors:** The regulation's clear risk classification system provides predictable pathways for investment. Investors can now assess whether a technology falls into the "provincial approval" bucket (lower regulatory risk, faster time-to-market) versus the "State Council approval" bucket (higher risk, longer timeline).
- **Liability Protection via Updated Consent Documentation:** Given that consent is voided upon emergence of new safety information, institutional review boards and sponsors must implement real-time risk monitoring systems to trigger re-consent processes