appendix

# Regulations on the Administration of Drug Clinical Trial Institutions

## Chapter 1 General Provisions

Article 1 In order to strengthen the supervision and management of drug clinical trial institutions, according to the "China Drug Administration Law of the People's Republic of China, Vaccine Administration Law of the People's Republic of China, Chinese Regulations on the Implementation of the Drug Administration Law of the People's Republic of China, Regulations on the Administration of Medical Institutions, and the CCP The General Office of the Central Committee and the General Office of the State Council "On Deepening the Reform of the Review and Approval System to Encourage Drugs" Opinions on Innovation of Medical Devices for Quality Products", to formulate these regulations.

Article 2 Drug clinical trial institutions refer to those with corresponding conditions and in accordance with the "Drug Good Clinical Practice (GCP) and Technical Guidance for Drug Clinical Trials Principles and other requirements, institutions that carry out drug clinical trials.

Article 3 To engage in drug research and development activities, to carry out economic activities within the territory of the People's Republic of China Clinical trials of drugs approved by the State Drug Administration (including equivalence test), which should be conducted in a drug clinical trial institution. drug clinical trials Inspection institutions shall meet the conditions of these regulations and implement record-filing management. Only carry out and drug clinical Institutions that analyze biological samples related to the test do not need to record.

Article 4 The drug supervision and administration department and the health and health department shall, according to their respective functions Responsible for the supervision and management of drug clinical trial institutions.

## Chapter II Conditions and Filing

Article 5 The basic conditions that a drug clinical trial institution shall meet include:

(1) Possess a practicing license for a medical institution, and have a second-class or above qualification,

The test site shall comply with the management of the campus (site) by the competent health department of the region where it is located.

stipulations. Specialties in conducting drug clinical trials with patients as subjects should be related to medical

The medical subjects of the institution's practice license are consistent with each other. Carry out phase I drug clinical trials in healthy subjects

The in-bed test and bioequivalence test shall be the specialty of the Phase I clinical trial laboratory;

(2) It has the technical ability of diagnosis and treatment suitable for conducting drug clinical trials;

(3) Having an independent workplace, independent and suitable for drug clinical trials

clinical trial pharmacy, independent reference room, and necessary equipment and facilities;

(4) Possess the ability to master drug clinical trial technology and related regulations, and be able to undertake drugs

Investigators of clinical trials; the principal investigators shall have senior professional titles and participate in

3 or more clinical trials of drugs;

(5) The professions that carry out drug clinical trials have similarities with undertaking drug clinical trials.

Adapted number of beds, outpatient and emergency services;

(6) Having the facilities, equipment, personnel and handling capacity for emergency and critical illness rescue;

(7) It has a special department responsible for the organization and management of drug clinical trials;

(8) Having a medical technology department suitable for conducting drug clinical trials, and entrusting medical

The institution undertaking the scientific testing shall have corresponding qualifications;

(9) Having an ethics committee responsible for the ethics review of drug clinical trials;

(10) It has a drug clinical trial management system and standard operating procedures;

(11) Having a management mechanism to prevent and deal with emergencies in drug clinical trials

regulations and measures;

(12) Medical personnel management and financial management prescribed by the competent health department

and other conditions.

Where a drug clinical trial institution is a disease prevention and control institution, it shall be at or above the provincial level

The disease prevention and control agency does not require the first, fifth and sixth items of the preceding paragraph of this article.

pieces.

Article 6 The State Drug Administration is responsible for establishing a "drug clinical testing machine"

Institutional filing management information platform" (referred to as the filing platform), which is used for drug clinical trial institutions

Registration and filing and operation management, as well as the drug supervision and management department and the health department

Information entry, sharing and disclosure of door supervision and inspection.

Article 7 Drug clinical trial institutions shall conduct their own or engage a third party

The technical level, facility conditions and characteristics of clinical trial institutions and professions shall be evaluated and evaluated.

It shall be filed after it is estimated that the requirements of this regulation are met.

Article 8 Drug clinical trial institutions shall, in accordance with the requirements of the filing platform, register the

households, complete the basic information form, and submit the medical institution practice license and other filing requirements

Qualification certification documents, the account will be activated after the approval of the filing platform, and the account will be activated according to the filing level.

The platform requires the organization and management structure, equipment and facilities, researchers, clinical trial majors,

Ethics committees, standard operating procedures and other filing information, uploading evaluation reports, filing

The station will automatically generate a record number.

The registered drug clinical trial institutions add clinical trial specialties, and should form a new

Add professional evaluation report, fill in relevant information and upload evaluation according to the requirements of the filing platform

Report.

Disease prevention and control institutions at or above the provincial level can select and evaluate territories with vaccine

Institutions with vaccination qualifications, as test site units, register and prepare on the filing platform.

For the case, the test site unit shall refer to the professional management of clinical trials.

Article 9 The authenticity of the information filled in the filing platform by the drug clinical trial institution shall be

bear full legal responsibility for its authenticity and accuracy. The name of the registered drug clinical trial institution

name, address, contact person, contact information, clinical trial major, principal investigator, etc.

This information is made public to the public and is subject to public inspection and supervision.

Article 10 The name, address, level of the institution, institution of the drug clinical trial institution

When the filing information such as the person in charge of the institution, the ethics committee, and the principal investigator changes,

The drug clinical trial institution shall fill in the required form in the filing platform within 5 working days.

Write and submit changes.

## Chapter 3 Operation Management

Article 11 After the drug clinical trial institution is put on record, it shall comply with the relevant laws and regulations.

Regulations and the requirements of the "Good Clinical Practice for Drugs", at the filing address and the corresponding special

Carry out drug clinical trials in the industry to ensure that the research is scientific, ethical, and

The authenticity, accuracy and completeness of the research data, ensure the traceability of the research process, and

bear the corresponding legal responsibilities. Disease prevention and control institutions conducting vaccine clinical trials shall

In line with the relevant guiding principles for the quality management of vaccine clinical trials, it is registered by the provincial-level or above disease

The disease prevention and control agency is responsible for the management of drug clinical trials and assumes major legal responsibilities

The test site unit bears direct legal responsibility.

Article 12 Drug clinical trials established or designated by drug clinical trial institutions

A special department for laboratory organization and management, coordinating the project management of drug clinical trials, and the experimental drug use

product management, data management, quality management and other related work, and continue to improve drug clinical trials

test quality.

Article 13 Drug clinical trial institutions shall have the rights of subjects in drug clinical trials.

responsible for the protection of interests. Ethics committee is responsible for reviewing drug clinical trial protocols

Academic and ethical rationality, review and supervise the qualifications of drug clinical trial investigators, supervise

Supervise the development of drug clinical trials and ensure that the ethical review process is independent, objective and fair.

The ethics committee shall comply with the requirements of the "Measures for Ethical Review of Biomedical Research Involving Humans".

Please disclose relevant information in the medical research registration information system, and accept the institution and the health

Management and public supervision of health authorities.

Article 14 The principal investigator shall supervise the implementation of drug clinical trials and the

the performance of the research personnel and the implementation of the measures to carry out the clinical trials of the drug

Quality management to ensure the reliability and accuracy of data.

Article 15 Phase I clinical trials of new drugs or high clinical risks require clinical trials

Closely monitored drug clinical trials should be conducted by tertiary medical institutions. vaccine clinical

Experiments should be carried out by tertiary medical institutions or disease prevention and control institutions at or above the provincial level

Or organize implementation. The registration applicant entrusts the registered drug clinical trial institution to carry out the drug

drug clinical trials, and can conduct the commissioned drug clinical trials by themselves or by hiring a third party

organization to evaluate.

Article 16 Drug clinical trial institutions shall prepare the

The case platform should fill in the summary report on the work of drug clinical trials in the previous year.

Article 17 Drug clinical trial institutions receive the information from overseas drug regulatory authorities

To check the requirements of drug clinical trials, the relevant information shall be entered into the preparation before accepting the examination.

The case platform, and the inspection result information will be entered within 5 working days after receiving the inspection result

filing platform.

## Chapter IV Supervision and Inspection

Article 18 The State Drug Administration and the National Health Commission shall establish

National Inspector Bank of Drug Clinical Trial Institutions, according to the needs of supervision and review, according to the position

Responsible for the supervision and inspection of drug clinical trial institutions.

Article 19 Provincial drug regulatory authorities and provincial health authorities

According to the self-assessment of drug clinical trial institutions, the conduct of drug clinical trials,

Past supervision and inspections, etc., organize clinical trials of drugs within the administrative region according to their responsibilities.

The inspection agency conducts daily supervision and inspection. For newly registered drug clinical trial institutions or

If the clinical trial specialty is increased or the address is changed, it shall be carried out within 60 working days.

The first supervision and inspection.

Article 20 Drug clinical trial institutions fail to comply with the "Quality Control for Drug Clinical Trials"

Those who do not comply with the “Regulations” shall be punished in accordance with Article 126 of the “Drug Administration Law”.

Article 21 If a drug clinical trial institution fails to file in accordance with these regulations, the state shall

The drug supervision and administration department does not accept the completed drug clinical trial data for use in drugs

Administrative License.

Article 22 Violating these regulations, concealing the true situation, having major omissions,

Provide misleading or false information or use other deceptive means to obtain recordation,

If there are defects and it is not suitable to continue to undertake drug clinical trials, its drug clinical trials will be cancelled.

The filing of the inspection institution or the relevant clinical trial specialty shall be handled in accordance with the law.

Article 23 The drug supervision and administration departments at or above the provincial level, and the health care departments at or above the provincial level

The competent health department shall, on the results of the supervision and inspection of drug clinical trial institutions and their handling, shall

Timely entry into the filing platform and public announcement.

## Chapter V Supplementary Provisions

Article 24 The format of the record number of a drug clinical trial institution is:

+4 digits for era + 5 digits for sequential number.

Article 25 The Health Bureau of the Logistics Support Department of the Central Military Commission, the Chinese People's Armed Police

The Health Bureau of the Logistics Department of the Police Force respectively conducted drug clinical trials of the military and the armed police.

Fulfill the supervision of the provincial drug regulatory authorities and health authorities in these regulations.

Supervision responsibilities.

Article 26 For special drugs such as drug addiction treatment, drug clinical trials should be carried out in specific institutions.

The bed test shall have the institutional qualification issued by the corresponding competent business department, refer to this regulation

fixed management.

Article 27 The drug supervision and administration department and the health department in charge of

No fee is charged for the filing and supervision and inspection of clinical trial institutions.

Article 28 These regulations shall come into force on December 1, 2019. "Drug Pro

Measures for the Qualification of Bed Testing Institutions (Trial)" (SFDA [2004] No. 44),

"Notice on Carrying out the Review and Inspection of Qualification Accreditation of Drug Clinical Trial Institutions"

(National Food and Drug Administration Note [2009] No. 203) and "Regarding the Issuance of Disposable Vaccine Clinical Trials"

"Notice on the Administration of Qualification Accreditation of Testing Institutions" (Food and Drug Administration [2013] 248

) shall be repealed at the same time.