A notice on the issuance of drug clinical trials, ethical review of the guiding principles

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Provinces, autonomous regions and municipalities directly under the Central Food and Drug Administration (Drug Administration), the General Logistics Department of the Ministry of Health and Drug Administration:

Strengthen the protection of the quality management of clinical trials and subjects, norms and guidance of the Ethics Committee of the drug clinical trials, ethical review and improve the quality of drug clinical trials, ethical review, according to the Drug Registration "and" clinical trial quality management practices, "the relevant provisions of the National Bureau of organizations to develop a drug clinical trials, ethical review of the work of guiding principles", is hereby issued. Board’s guidance to drug clinical trials will be learned and implemented.

Appendix: Guiding Principles of drug clinical trials, ethical review, drafting instructions

Drug clinical trials, ethical review of the Guiding Principles

Chapter I General Provisions

Article 1 In order to strengthen the guidance and supervision of the ethical review of clinical trials, standardize ethics clinical trials review of ethics committee to ensure that drug clinical trials to meet the scientific and ethical requirements, according to the "quality of drug clinical trials management
practices (GCP), World Medical Association Declaration of Helsinki, the Council of International Organizations of Medical Sciences “biomedical research involving human International Ethical Guidelines” to develop the guiding principles.

Article 2 In order to ensure the dignity, security and interests of the participants, promoting the drug clinical trials develop scientifically and healthily, and enhancing public trust in clinical trials, the ethics committee should review the science and ethical rationality of drug clinical trial program.

Article 3 In compliance with the state constitution, laws, regulations and relevant provisions, the Ethics Committee must carry out independent ethical review of clinical drug trials, and accept the guidance and supervision of drug supervision and administration departments.

Article 4 An inspection and evaluation system need be established by the drug supervisory and administrative departments to implement the guidance and supervision and management of the ethical review to the ethics committee.

Chapter 2 Organization and management of the Ethics Committee

Article 5 The formation of the Ethics Committee should be consistent with relevant state regulations.

The ethics committee should be made up by multi-disciplinary background staff, including those engaged in medical professionals, non-medical professionals, legal experts, as well as the staff of independent research/test units, at least five people and gender balance.
Ensure that the Ethics Committee review and evaluate the test of scientific and ethical rationality with qualifications and experience commonly.

The composition and work of the Ethics Committee should not be affected by the participants in the trial.

Article 6 Written documents need be set about the organizational structure of the Ethics Committee, the duties of the authorities and Ethics Committee, the qualification requirements of the team members, qualifications and term in the office, office duties, the establishment of selection and the appointment of members of the Ethics Committee and the procedures of Secretary.

Article 7 The institution/department who form the Ethics Committee shall provide the necessary support to the Committee.

Establishment of an independent office, with the necessary conditions for the office, to ensure the confidentiality of the communication with the applicant and related documents.

Article 8 Ethics Committee members can be used the way of recruitment or recommendation.

The ethics committee needs one chairman, several vice chairmen, elected by the Ethics Committee.

Article 9 The Ethics Committee members should agree to disclose their names, occupations and affiliations, to sign the review, the subjects of information and related matters of confidentiality agreements, conflict of interest declaration.
Article 10 Ethics Committee can hire an independent consultant or permanent appointment of an independent consultant.

Reply to the invitation of the Ethics Committee, the independent consultant provide advice of some problems in the pilot program to the Ethics Committee, however, the independent consultant does not have the right to vote of ethical review.

An independent consultant can be ethical or legal aspects, specific diseases or methodologies expert, or on behalf of a particular region/ a specific disease population/ethnic groups or other specific interest groups.

Article 11 The Ethics Committee should establish a training mechanism focus on continuing education for new members and members of the, organize GCP and other related laws and regulations, ethical review of drug clinical trials and standard operating procedures of Ethics Committee.

Article 12 Ethics committee should develop standard operating procedures and systems to ensure that the normative and consistency of ethical review.

Include at least the following aspects:

(A) The formulation of standard operating procedures and ethical review application guide;

(B) The organization and management of the Ethics Committee: the establishment of the Ethics Committee, security measures of the ethical review, the management of conflicts of interest, members and staff training, an independent consultant selection;

(C) The styles of the ethical review: The meeting reviewed and an emergency meeting to review, an expedited review;
(D) The process of ethical review: the acceptance and treatment of review applications, the initial review, tracking review, review the communicate of decision;

(E) Meeting management: meeting preparation, meeting procedures, meeting records;

(F) Management of document and file: archiving, preservation, inspection and copying.

Chapter 3 Duties requirements of the Ethics Committee

Article 13 The ethics committee should be based on the needs of the ethical review and constantly improve the organization and management and institutional building to fulfill the duties of the safety and interests of the protection of subjects.

Article 14 Ethics committee should review the ethical issues submitted by the applicant with independent, impartial, fair and timely manner.

In addition to review all drug clinical trial programs of its own institutions, the Ethics Committee can also review the clinical trial program commissioned by other agencies.

Article 15 Ethics Committee review of the clinical trials of the drug supervision and may exercise the following powers:

(A) To approve/not approve a drug clinical trial;

(B) Track review to an approved clinical trials approved;

(C) Termination or suspension of clinical trials that have been approved.

Article 16 Ethics Commission should be filed timely to the State Food and Drug Administration and food and drug supervision and management departments of the local province.
The following records information should be submitted: the list of ethics committee chairman and members (with resume), the Articles of Association of the Ethics Committee, the Ethics Committee working procedures and systems.

Article 17 of the Ethics Committee should the State Food and Drug Administration and the seat of the provincial food and drug supervision and management departments reporting year, the ethical review.

Chapter IV Application and Acceptance of ethical review

Article 18 The Ethics Committee for ethical review of the applicant to provide consulting services relating to matters of ethical review and examination of the application the required application forms, informed consent and other documents, templates; Ethics Committee should be on the admissibility of the application for ethical review related matters clearly defined.

(A) should be clearly submitted to ethical review must file directory and review of the required number of copies;

(B) should be clearly accepted the basic requirements, review the application forms, standards, time limits and procedures;

(C) should be made clear submission and accepted the change request, the supplementary application of the basic requirements, time limits, procedures, documents, conditions and requirements.

Article 19 The Ethics Committee of the receipt of applications for ethical review of the applicant for the review of the submitted documents are incomplete or do not meet the requirements, it should be a one-time inform the ethical review applicant to make corrections.
The ethics committee accepted the expected time of application for ethical review should inform the applicant of ethical review meetings.

Provisions and requirements of the Ethics Committee of 20 ethical review applicant is required to ethical review applications submitted to the Ethics Committee. Submitted to the ethics review for the application documents, including (but not limited to the contents of the file):

(A) ethical review application form (signed and dated);

(B) clinical trials program (specify the version number and date);

(C) informed consent (specify the version number and date);

(D) the recruitment of subjects related materials;

(E) of the case report form;

(F) the investigator’s brochure;

(Vii) the principal investigator curriculum vitae;

(H) the State Food and Drug Administration Clinical Trial Approval ";

(9) Other Ethics Committee of the description of the important decisions to apply for research projects should provide the reasons for a negative conclusion;

(10) Test drugs qualified inspection reports.

Article 21 The Ethics Committee decided to accept the review of the project, select a member of the trial, if necessary, by an independent consultant.

Chapter Ethics Committee of the ethical review
Article 22 of the Ethics Committee should be required to convene a review meeting required statutory number of people to the meeting. At least to the number of members should be more than half of the members, and not less than five people. Members to the meeting should include a medical professional, non-medical professional, independent of the outside of the unit of research/testing personnel, staff of different gender.

Article 23 of the chairman (or authorized) presided over the ethics committee meeting. Necessary, invite the participants of an independent consultant to provide advice; principal investigator/sponsor to attend the meeting described the program or to elaborate on the specific problem. The Secretary of the Ethics Committee meeting to discuss the content and review of decisions should be summarized and the formation of the meeting. Meeting should be the ratification process.

Article 24 of the Ethics Committee to establish a "trial" system: the Ethics Committee in accordance with the principles of professional and ethical issues related, can be specified for each item or two officiating trial members.

Article 25 of the Ethics Committee review session, to examine the major review of the way. Can be implemented quick review of the following circumstances:

(A) small correction of the clinical trial program has been approved by the Ethics Committee, does not affect the trial of the risk benefit ratio;

(B) have not been included in the subjects, or have completed the year of the pilot project interventions/Regular follow-up;

(C) review of the expected serious adverse events.

Article 26 fast review by one or two members responsible for the review. Quickly agreed to review the pilot project should be informed of the next Ethics Committee meeting. Some of the
following circumstances, quick review of the project shall be transferred to the conference review:

(A) Review of negative views;

(B) two members of the disagreement;

(C) Members raised the need for a conference review.

Article 27 of the course of the study appear in the major or serious problems that threaten the safety of the subjects, the Ethics Committee shall convene an emergency meeting to review and, where necessary, take appropriate measures to protect the safety and interests of subjects.

Article 28 of the main content of the ethical review (Appendix I):

(A) the design and implementation of research programs;

(B) The trial of the risks and benefits;

(C) the recruitment of subjects;

(D) informed consent of the book to inform the information;

(E) The informed consent process;

(F) health care and protection of subjects;

(G) privacy and confidentiality;

(8) involves the study of the vulnerable groups.

Article 29, the Ethics Committee response to the ethical review of the quality of management and control of the program and agenda of the Conference on ethical review should be required to review document should be fully discussed, to ensure that members on the issues discussed in order to ensure the quality
of ethical review and the Review Conference able to fully express their different views.

Article 30 The ethical review meeting should pay particular attention to test the scientific, security, fairness, subjects protection, informed consent of the instruments and the informed consent process, conflict of interest issues.

Article 31 of the multi-center clinical trial ethical review should be based on the consistency and timeliness of the review of basic principles. The multi-center clinical trial to establish a collaborative review process:

(A) The head of the unit ethics committee responsible for review of the pilot program of scientific and ethical rationality.

(B) under the premise of the head of the unit ethics committee review comments, the participating units ethics committee responsible for review of the trial in the feasibility of this institution, including institutional researchers qualifications, experience, and whether there is sufficient time to participate in clinical testing, staffing and equipment conditions. Participate in the Unit Ethics Committee has the power to approve or disapprove the research conducted in their institutions.

(C) to participate in the unit ethics committee review of the proposal must be made to amend the proposal should form a written document and communicate the information to the sponsor or the testing body responsible for the pilot scheme, for its consideration and consensus to ensure that the centers follow the same pilot programs.

(D) of the Ethics Committee of each center to deal with the institutions conducting clinical trials track review. Serious adverse events occurred, the Ethics Committee of the institution shall be responsible for timely review, and review comments
communications sponsor. Based on the subjects of security considerations, the ethics committee of each center are entitled to terminate the test to continue in their institutions.

(E) The head of the unit tracking review comments on the clinical trials should be timely so that all participating units for the record.

Chapter VI of the ethical review of the decision served

Article 32 Conference on ethical review of a decision to vote the way, with more than half of the views will be members as the Ethics Committee to review the decision.

Article 33 of the Ethics Committee for review of decision should be consistent with the following conditions:

(A) of the complete application documents;

(B) to a member of the quorum requirement;

(C) follow the review process, the review points to conduct a comprehensive review and full discussion;

(D) discussion and voting, the departure of members of the applicant and the conflict of interest;

(E) The member may not participate in the review meeting by the other members instead of voting.

Article 34 approved clinical trial program must be at least meet the following criteria:

(A) the expected risk of the test to take appropriate risk control and management measures;

(B) the risk of subjects relative to the expected benefit is reasonable;
(C) the choice of subjects is fair and equitable;

(D) informed consent to inform the full information, obtain the informed consent process compliance;

(E) If necessary, the pilot program should have adequate data and safety monitoring plan to ensure the safety of subjects;

(F) to protect the privacy of subjects and to ensure confidentiality of the data;

(G) involves the study of vulnerable groups, with a special protective measures.

Article 35 of the Ethics Committee review comments of the following circumstances:

(A) consent;

(B) the necessary amendments agreed to;

(C) make the necessary corrections after a retrial;

(D) do not agree with;

(E) termination or suspension of clinical trials that have been approved.

Article 36 of the Ethics Committee Secretary shall organize the meetings in a timely manner after the meeting, according to conference proceedings and conclusions of the review formed the written views of the ethical review/approval documents. Views of ethical review/approval documents should be chairman (or authorized) signature and seal of the Ethics Committee. Ethical review comments/documents relating to information, including:

(A) basic information
A pilot project information: project name, sponsor, and review comments/approval document number;

(2) institutions conducting clinical trials and researchers;

Meeting information: meeting time, location, review category, review documents, including clinical trial protocol and informed consent should be marked with the version number/date;

Ethical review of the issue date of the approval documents/opinions;

Ethics Committee contacts and contact information.

(B) review the opinions and decisions

(1) review the decision to "agree" at the same time inform the Ethics Committee of the implementation of tracking the review;

The review decided to "make the necessary amendments to agree" and "mutatis mutandis to a retrial", detailing the amendments to inform and re-submit the program requirements and processes;

3 Review of the decision to "disagree" and "termination or suspension of clinical trials that have been approved" must fully explain the reasons and inform the applicant in respect of matters related to an explanation or a complaint.

Article 37 of the ethics review comments/documents issued by the ethics committee chairman (or authorized) audit after the signing, should be promptly communicated to the applicant.

Track review of Chapter VII of the ethical review

Article 38 The Ethics Committee responsible for all clinical trials approved by track review until the end of the trial.
Amendment to Article 39 review is a review of any changes during the test pilot program. Any modification of the pilot program during the test shall be submitted to the Ethics Committee for examination and approval before implementation. The Ethics Committee shall require the sponsor and/or researchers to submit the amendment to review the relevant information, including (but not limited to):

(A) modify the content and modify the reasons for that;

(B) to amend the proposal on the expected risk and benefit;

(C) to amend the proposal on the interests and security of subjects.

Ethics Committee for the test program to modify risk and benefit assessment, to make the review comments. In order to avoid the emergency caused by injury subjects to amend the proposal, the researcher can be submitted to the Ethics Committee for examination and approval before implementation, after a written report to the Ethics Committee in a timely manner.

Article 40 of the Annual/Regular follow-up. Initial review of the ethics committee should be based on the test the degree of risk, the decision of the year/track the frequency of review on a regular basis, at least once a year. Ethics committee should require researchers to submit their reports, annual/regular follow-up review of information including (but not limited to):

(A) the progress of the trial;

(B) the number of subjects included in the cases, the number of completed cases, the number of exit cases;

(C) confirm that the serious adverse events reported in a timely manner, properly handle;
(D) may affect the risk benefit that any event or new information.

The risks and benefits of the ethics committee to review research progress, the re-assessment test.

The review of Article 41 serious adverse events is a review of the sponsor and/or researchers report serious adverse events, including the extent and scope of the serious adverse events, the beneficial effect on the test risk, as well as the subjects of health protection measures.

Article 42 The non-compliance/violation of the review of the program refers to the events in clinical trials, non-compliance/violation of program review. The Ethics Committee shall require the sponsor and/or researchers to be a description of the event causes, effects and treatment measures, to review whether the event affects the safety and interests of subjects, whether the impact test the risk-benefit.

Article 43 review of the early termination of the test refers to the early termination of the test’s review of the sponsor and/or researchers. The Ethics Committee shall require the sponsor and/or researchers report the reasons of early termination of the experiment, as well as the subsequent treatment of the subjects, review the safety of subjects and interests guaranteed.

Article 44 review of the node title is a review of the concluding reports of clinical trials. The Ethics Committee shall require the sponsor and/or the researchers report test completion, review the safety of the subjects and the protection of the rights.

Article 45 of the track to review the decision and the reasons should be promptly communicated to the applicant.

Chapter VIII of the ethics committee review document management
Article 46 The ethics committee should be independent of the archive management system. Ethics Committee of the archiving archive files, including files and project review documents.

Article 47 of the Ethics Committee documents include (but are not limited to):

(A) the work of the ethics committee system, job responsibilities, standard operating procedures and ethical review application guidelines;

(B) the members of the Ethics Committee document of appointment, members of the curriculum vitae and training records, as well as members signed a confidentiality agreement and the interests of conflict statement;

(C) of the Ethics Committee of the annual work plan and summary.

Article 48 of the Ethics Committee of the pilot project review document include:

(A) submitted for review materials submitted by the investigator/sponsor;

(B) ethical review worksheet, the meeting attendance sheet, the voting list, minutes of meetings, ethics committee approval documents/comments, and related communication letter.

Ethical review document should take good care of to five years after the end of the clinical trial, or to extend the shelf life in accordance with the relevant requirements. Archive file directory Annex 2.

Article 49 of the Ethics Committee response to the inspection and copying of files to make the relevant provisions in order to ensure the security and confidentiality of the document file.

Chapter IX Supplementary Provisions
Article 50 of the Ethics Committee can be established between the information exchanges and cooperation mechanism to promote the improvement of ethical review capacity.

Article 51 The guiding principle has been established prior to the implementation of the Ethics Committee, it should be within one year from the date of this guiding principle with reference to the relevant requirements of the guiding principles to improve the organization and management system construction and the State Food and Drug Administration and the province level food and drug administration departments for the record.

Article 52 of the guiding principles for the purposes as of the date of promulgation.

Appendix 1:

The main content of the ethical review

A test program design and implementation

1.1 test conform to generally accepted scientific principles, based on literature as well as adequate laboratory studies and animal experiments.

1.2 and the test purposes of experimental design and the control group setting reasonable.

1.3 subjects early exit test standards, suspension or termination of the test standards.

1.4 Audit and Inspection and audit plan in the trial process, including, if necessary, establishment of an independent Data and Safety Monitoring Board.
1.5 Qualifications and experience of researchers, and have sufficient time to carry out clinical trials, staffing and equipment conditions to meet the test requirements.

1.6 clinical test results reported and published.

2 test of the risks and benefits

The nature, extent and probability assessment of the risk of the 2.1 test.

2.2 Risk in the extent possible, minimized.

2.3 is expected to benefit from the assessment: participants benefit and social benefit.

2.4 test risks and benefits of rationality: (1) directly benefit from the prospect of test subjects, the expected benefit and risk should be at least with the currently available alternative treatment benefits and risks fairly. Test the risk for subjects anticipated benefits must be reasonable; ② The test subjects did not directly benefit from the prospects, the risk benefit for society is expected in terms must be reasonable.

(3) recruitment of subjects

3.1 subjects of the population characteristics (including gender, age, race, etc.).

3.2 trials to benefit and risk in the target disease population a fair and equitable distribution.

3.3 recruitment methods and methods to be taken.

3.4 inform the way the test information to the subjects or their representatives.

3.5 subjects inclusion and exclusion criteria.
(4) informed consent of the book told

4.1 The purpose of test, the test procedure to be followed (including all invasive procedures), the test period.

4.2 is expected to subjects of the risks and inconveniences.

4.3 is expected to benefit. Should be informed of the subjects when the subjects did not benefit directly.

4.4 subjects available alternative treatment options for the treatment of important potential risks and benefits.

4.5 subjects to participate in the trial whether or not to receive remuneration.

4.6 subjects participating in the pilot whether to bear the costs.

4.7 can identify the subjects identity of the record level of confidentiality and, when necessary, the sponsor of the pilot project, the Ethics Committee, government departments can access the data of subjects participating in the trial as required.

4.8 In the event of damage trial, subjects can get treatment and appropriate compensation.

4.9 participate in the trial is voluntary, and can refuse to participate or have the right to withdraw at any time in any stage of the experiment the test would not be subject to discrimination or retaliation for their medical treatment and rights will not be affected.

4.10 When the trial, and subjects the right to exist, and a trial related injuries, contact and contact.

(5) the informed consent process
5.1 The informed consent should be consistent with fully informed and fully understand the self-selection principle.

5.2 Informed Consent of the representation should be easy to understand, suitable for the level of understanding of the subjects groups.

5.3 how to obtain informed consent are described in detail, including who is responsible for obtaining informed consent, and informed consent requirements.

5.4 The plan incorporates not express informed consent as subjects when justified, legitimate, or authorized to agree to a detailed description of how to obtain informed consent.

5.5 In the course of the study to listen to the provisions of questions and comments and reply to the subjects or their representatives.

Health care and protection of subjects

6.1 Researchers qualifications and experience and testing requirements to adapt.

6.2 For test purposes without giving the reasons of the standard treatment.

6.3 In the testing process and the end of the trial, subjects provided medical coverage.

6.4 For the subjects to provide appropriate medical monitoring, psychological and social support.

6.5 measures to be taken when the subjects voluntarily withdrew from the study.

6.6 extend the use of emergency or out of compassion to provide the standard of the trial medication.
After the end of the 6.7 test, whether to continue to provide the participants the instructions of the trial medication.

6.8 subjects were required to pay the costs of instructions.

6.9, the subjects of compensation (including cash, services, and / or gifts).

6.10 compensation due to participate in the trial resulting in injury / disability / death of the subjects or treatment.

6.11 Insurance and damages.

Privacy and confidentiality

7.1 can access the subjects personal information (including medical records, biological specimens), staff requirements.

7.2 to ensure the confidentiality and security measures of the subjects personal information.

8 trials involving vulnerable groups

8.1 only as subjects of the vulnerable populations, the test well.

8.2 trials for the vulnerable groups of specific diseases or health problems.

8.3 When the test subjects for vulnerable groups do not provide benefit may test risk is generally not greater than minimal risk, unless the Ethics Committee agreed that the level of risk can be increased slightly.

8.4 when the subjects were unable to give fully informed consent, to obtain informed consent, his legal representative, if possible, should also obtain the consent of the subjects I
9 involves specific disease groups, specific regional population / ethnic test

9.1 The trial population of specific diseases, specific regional population / ethnic groups.

9.2 external factors on individual informed consent.

9.3 During the experiment, the plan to the crowd for consultation.

9.4 The test of local development, such as strengthening local health care services, to enhance research capacity and ability to respond to public health needs.

Appendix 2:

**Ethics Committee archive file directory**

A management file class

1.1 ethics committee work system and personnel duties.

1.2 Ethics Committee of the professional curriculum vitae, document of appointment.

1.3 Ethical Committee of the training documents.

1.4 Ethical review of the Application Guide.

1.5 Ethics Committee Standard Operating Procedures.

1.6 clinical trials ethical issues review of technical guidelines.

1.7 fund management files and records.

1.8 annual work plan and a summary of the work.

Project review file class
2.1 review of materials submitted by the applicant.

2.2 Notification of Acceptance.

2.3 Ethics Committee reviewed the work table.

2.4 Ethics Committee meeting agenda.

2.5 Ethics Committee meeting attendance sheet.

2.6 Ethics Committee of the voting list.

2.7 Ethics Committee meeting.

2.8 Ethical review comments / ethical review of this document.

2.9 The ethical review of the applicant’s responsibility statement.

2.10 Ethics Committee and the applicant or other relevant personnel on the application, review and track the review of the correspondence.

2.11 tracking the relevant documents of the review.
Special disease groups, specific regional population/ethnic groups (Community): the crowd has a common feature, the feature can be the same/similar regions, or the same values, or common interests, or suffering from the same disease.

Confidentiality (Confidentiality): to prevent the ownership-related information or personally identifiable information is disclosed to no right to know.

Conflict of interest (Conflict of Interest): When a member of the Ethics Committee with the review of the pilot project between the relevant interests, and thus affect his/her point of view of protection subjects to make an impartial and independent review of the test. Conflict of interest common to a member of the Ethics Committee review the project on the economic, material, institutional and social relations of interest.

Data Safety Monitoring Board (Data and Safety Monitoring 板: the sponsor is responsible for the establishment of an independent Data Safety Monitoring Board, whose duty is to regularly assess the progress of the trials, analysis of safety data, as well as important indicators of the effects of, and the sponsor of pilot continue or be amended, or early termination of the recommendations.

Ethics Committee (Ethics Committee of Institutional Review Board): by medical professionals, legal experts and non-medical staff, an independent organization, its responsibilities for the verification of clinical trial programs and accessories ethical, and to provide public assurance to ensure that subjects the safety, health and rights are protected. The composition of the Committee and all activities should not be subject to interference or influence of the organization and implementers of clinical trials.
Informed consent (Informed Consent): point the subjects informed of all aspects of a trial, the subjects voluntarily confirm their consent to participate in the clinical trials process, shall be signed and dated informed consent as the documentary evidence.

Informed consent (Informed Consent Form): Each subject volunteered to participate in a trial documentary evidence. Researchers need to explain to the subjects on a trial basis, test purposes, the possible benefits and risks, other treatment methods are available, as well as comply with the provisions of the Declaration of Helsinki, the subjects of rights and obligations of the subjects to fully understand after the expression of their consent.

Minimal risk (Minimal Risk): the trial is expected to risk the possibility and extent of not more than the daily life or routine medical examination or psychological test risk.

Multi-center clinical trial (Multicentre Trial): follow the same program in more than one test center, respectively, by a number of researchers responsible for the implementation of the completed clinical trials.

Do not comply with/against program (Non-compliance/Violation): refers to the ethics committee approved all deviate from the pilot program, and this deviation did not get the prior approval of the Ethics Committee, or non-compliance/violation of human subjects protection regulations and ethics committee requirements.

Amendments (Protocol Amendment): a written modification or clarification of the pilot program, as well as the organization and implementation of the trial documents and information.

Statutory number (the Quorum): provisions for review and decision on a particular test must attend a meeting of the Ethics Committee of the number of members and eligibility requirements,
effective meetings should be attended by the number of members and eligibility requirements.

Subjects (Research the participants is): individuals to participate in biomedical research can be used as the experimental group or control group, or the observation group, including healthy volunteers, or directly related to the voluntary participants to test the target population, or from the study drug for the sick people.

Standard operating procedures (Standard the Operating Procedure, SOP): To ensure the implementation of consistency so as to achieve a specific purpose to develop a detailed written instructions.

Serious adverse events (Serious Adverse Event): the clinical trials process to require hospitalization, prolonged hospitalization, disability, affecting the ability to work, endangering the life or death, resulting in congenital malformations and other events.

Unexpected adverse events (Unexpected Adverse Event): nature, severity or frequency of adverse events, unlike the previous program or other relevant information (such as the investigator’s brochure, drugs) described the expected risk.

Vulnerable groups (Vulnerable Persons): relative (or absolute) can not afford to maintain his own advantage, usually refers to those abilities or restrictions on the freedom not to give consent or refuse consent, including children, because mental disorders can not be given informed consent.