Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans (2020 Edition)

National Health Commission Medical Ethics Expert Committee Office

Chinese Hospital Association

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Preface to Part One

Medical research using humans as subjects aims to obtain medical knowledge, clinical diagnosis and treatment methods, and medical treatments that can be generalized to better meet the public's medical and health needs. Clinical research should pay special attention to solving health problems that have unmet medical and public health needs, and its social mission is to prevent and alleviate human suffering caused by diseases and injuries. Clinical research using humans as subjects is necessary for the development of medicine. It is not only ethically allowed but also ethically required. Only when subjects are fully respected and protected can clinical research be ethically justified, which is also conducive to the healthy development of medicine and science. A

scientifically unreliable research design is necessarily unethical because it exposes research subjects to the risks of participating in the research without obtaining reliable scientific knowledge. Therefore, the research design must comply with scientific principles generally accepted by the scientific community and be supported by scientific evidence, so that the research results are reliable. Subjects participating in clinical studies believe that these studies have passed the scientific verification of basic research, that the potential benefits and possible risks of participating in clinical studies are within a reasonable range, and that doctors believe in what they believe when making major medical decisions in the future. The research evidence based on these is rigorous and fair and objective.

Clinical researchers have primary responsibility for subject protection. Research should be conducted in a responsible manner by competent researchers and should never put subjects, especially medically fragile subjects, at risk to validate medical knowledge. Research should not be conducted in order to obtain more clinical scientific knowledge, and the safety of subjects in current studies at the expense of the health of the majority of future patients.

During the study, subjects should be provided with accurate information about the current status of the clinical research and possible risks, and valid informed consent should be obtained from subjects with full decision-making capacity. For subjects who lack the ability to make complete decisions on their own, consent from their legal guardian should be obtained. The main responsibility of the ethics

review committee and ethics review is to protect subjects in research projects that meet scientific and social values. All clinical research projects must be reviewed by the Ethics Review

Committee for their scientific value and ethical defensibility before being carried out, and can only be implemented after obtaining approval from the Ethics Review Committee. The ethics review committee will further follow up and review the project as needed during the implementation of clinical research and supervise the research process.

In order to further standardize clinical research and continuously strengthen the institutional construction and capacity building of ethics review committees, under the leadership and guidance of the National Health Commission, the Medical Ethics Expert Committee of the National Health Commission and the Chinese Hospital Association took the lead in establishing my country's clinical research ethics review committee. and assessment guides to promote the development of industry standards through third-party industry organizations. These guidelines are consistent with the "Ethical Review Measures for Biomedical Research Involving Humans" promulgated by the former National Health and Family Planning Commission, the "Guiding Principles for Ethical Review of Drug Clinical Trials" promulgated by the former State Food and Drug Administration, and the "Guiding Principles for Ethical Review of Drug Clinical Trials" promulgated by the State Administration of Traditional Chinese Medicine The "Code for Ethical Review and Management of Clinical Research in Traditional Chinese Medicine" as well as the "Declaration of Helsinki" formulated by the World Medical Association and the "International Ethical Guidelines for Research Involving Human Health" formulated by the International Council for Medical Sciences. Guidelines for Health-related Research Involving Humans) and other international and domestic general ethical guidelines maintain a high degree of consistency and are more operable.

Part 2 Construction Guide

Chapter 1 Purpose and Principles of the Ethical Review Committee

1. Purpose of the Ethical Review Committee

The Ethical Review Committee conducts prior review of all clinical medicine and health research projects that use humans as subjects, puts forward modification requirements and approves them, conducts follow-up reviews of ongoing projects, and conducts scientific and ethical review of research projects. It plays a supervisory role in ensuring compliance with relevant international and domestic norms and guidelines. Its purpose is to protect the rights and welfare of research subjects.

2. Review principles of the ethics review committee

(1) Respect and protect the prospective research subjects' consent to participate in the research. The right to make the right decision, strictly implement the informed consent procedure, prevent the use of deception, improper inducement, coercion (including disguised coercion) and other improper means to recruit research subjects, and allow research subjects to withdraw their consent to participate in the research at any stage of the research without will be

treated unfairly. (2) Consideration of the safety, health and rights of research subjects must be more important than the consideration of the acquisition of scientific knowledge and the overall benefit to society, and strive to maximize the benefits to research subjects and avoid as much as possible

greater than the lowest risks. (3) Exempt the research subjects from the financial burden they bear due to the benefits during the trial. Respect and protect the private information of research subjects, truthfully inform the storage and use of the private information of the research subjects (including possible future use) and confidentiality measures, and do not disclose the privacy and sensitive information of the research subjects without valid authorization. personal information Leak to unrelated third parties or media.

(4) Ensure that research subjects receive timely and free treatment and corresponding compensation or compensation when they suffer injuries directly related to their participation in research. (5) Special protection

should be given to vulnerable groups such as research subjects who have lost or lack the ability to protect their own rights and interests, desperate patients suffering from serious diseases without effective treatments, and those with low socioeconomic status and low educational level.

(6) Biomedical clinical research must pass ethical review. New biomedical technologies that are expressly prohibited by national laws, regulations and relevant regulations, and that have major ethical issues, and have not been proven safe and effective by preclinical animal experiments, shall not be subject to clinical research.

3. Supervision Responsibilities

(1) Medical institutions are responsible for the clinical research conducted in their own institutions. Medical institutions can also entrust a department within the authorized institution to perform supervisory responsibilities and accept complaints about research subject protection issues during research.

(2) The medical institution or authorized regulatory department is responsible for organizing and managing the work of the ethics review committee and providing supportive work guarantees, including providing necessary human resources, working environment, facilities and equipment, working hours and financial support, and Responsible for providing opportunities and financial support for scientific research ethics training for committee members. Ethical review committee members should be reasonably compensated for their time and effort. All relevant regulatory measures should be recorded in writing. (3) Medical institutions or authorized regulatory authorities should avoid administrative interference with the review work.

Intervene to ensure the independence of ethical review work and moral judgment.

Chapter 2 Organization and Management of Ethics Review Committee

1. Composition of the Ethics Review Committee

(1) The ethics review committee should be composed of members with multi-disciplinary professional backgrounds, which may include experts and scholars in the medical field and research methodology, ethics, law and other fields. There should be one committee member who is not affiliated with the institution and not closely related to the project researchers (the same committee member may meet both requirements). The number of persons shall not be less than 7. Experts in special fields can be hired as independent consultants when necessary. There should be clear rules and regulations on the qualifications, hiring procedures and work responsibilities of independent consultants, and the hiring process of independent consultants should be recorded and recorded (put in the file record content). (2) Medical institutions should establish an

independent administrative department directly subordinate to the medical institution.

A well-established ethics review committee office is established to ensure that the ethics committee can independently carry out ethical review work. The office should be equipped with full-time (part-time) secretaries and staff who are qualified to perform the work according to the actual needs of the review work. (3) The ethics review

committee should be able to independently review and approve research projects that comply with the guidelines in terms of scientific value, social value and protection of research subjects in accordance with regulations, ethical standards and relevant regulations. (4) The ethics review committee should promptly update

the list of ethics review committee members, contact information, changes in personnel appointments, etc., and submit them to the institution or the department authorized to supervise the ethics review committee for filing, and complete the National Health and Medical Commission and the National Drug Administration in accordance with regulations. Filing procedures required by the National Supervisory Authority (NMPA).

2. Member Qualifications

All members should undergo basic professional training in scientific research ethics before starting work.

Train and obtain a scientific research ethics training certificate at the provincial level or above. Committee members participating in the ethical review of drug clinical trials should obtain a GCP training certificate recognized by the State Food and Drug Administration as required. Committee members should have strong awareness of scientific research ethics and ethical review capabilities, and should participate in and obtain special training on scientific research ethics at or above the provincial level (including provincial level) at least once every 2 years.

Certificate, as well as participating in continuing education training on research ethics (including online or offline) and obtaining credits, of which Category I credits should be no less than 5 points to ensure that ethics review capabilities are continuously improved. **3. Committee appointment procedure and term of office**

(1) The medical institution is responsible for recommending candidates for the chairman, deputy chairman and other members of the ethics review committee. The chairman and deputy chairman of the ethics review committee should have high prestige and reputation within the medical institution, and their recommendation can also be decided by the members of the ethics review committee through consultation. The legal representative or department of a medical and health institution

The person in charge of the research department shall not serve as the chairman/deputy chairman. All committee selection procedures are documented. The filing includes recommended positions and terms of office, as well as resumes of all committee members.

(2) The term of each member shall not exceed 5 years and may be re-elected. There is no limit to the maximum term. When a member leaves office, the secretary of the ethics review committee should promptly notify the institution or authorized competent authority. The re-election of members shall be carried out in accordance with procedures and shall be recorded.

(3) If the Ethics Review Committee needs to dismiss members who have not yet expired, they must explain the reasons for their failure to perform their duties (such as frequent absence from meetings, inappropriate behavior, or unresolved conflicts of interest, etc.). The ethics review committee should make a removal resolution and submit an application to the competent authority for early termination of the member's term, which needs to be approved. If a member accepts the removal resolution of the Ethics Review Committee, the competent department of the Ethics Review Committee shall issue a written notice of removal to the member.

4. Responsibilities of committee members

(1) Responsibilities of the Chairman: 1.

Preside over the meeting

and review all human rights issues in accordance with international and domestic scientific research ethics standards and management requirements.

For research projects involving human subjects, it is urged that each committee member should have the opportunity to participate in the ethical review resolution process;

2. Understand and determine whether the conflict of interest

inquiry committee member has a conflict of interest with the pilot project. If a conflict of interest exists,

It is necessary to determine whether to (1) disclose the conflict of interest within the committee; or (2) require the member to recuse himself from the review of the relevant research proposal and not participate in voting.

3. Ensure that the review report on the trial protocol submitted by the researcher and the chief review committee to the ethics review committee follows the review guidelines of the ethics review committee, including in detail consistent with international and domestic scientific research ethics standards.

4. The chairman can make decisions based on the professional background, review ability and projects to be reviewed.

In the professional field, one or several committee members are designated for the project to focus on reviewing certain research plans before the meeting review (main review system), and then submit the review report to the ethics review committee for meeting review. 5. Ensure that the ethical review committee conducts initial meeting

review and review of all trial protocols. 6. Provide work guidance and professional guidance to committee members, scientific researchers and other

relevant personnel on clinical research involving human subjects, and collaborate with all committee members to perform the functions of the ethics review committee at a high level. 7. Promptly notify relevant newly promulgated and formulated international and domestic policies and ethical standards to ensure that members have the opportunity to learn and improve

their review capabilities in order to enhance their understanding of ethical standards and norms.

(2) Responsibilities of the Deputy Chairman: In

the absence of the Chairman, he shall perform all duties established by the Chairman. (3) Responsibilities of

committee members

1. Make full preparations for the agenda items of the meeting, regularly participate in review meetings, accurately review the contents of the meeting, review the research project and make review resolutions.

2. Members of the ethics review committee should sign a confidentiality agreement and promise to fulfill confidentiality obligations for the ethical review work they undertake, and to keep confidential the accepted research project plans, subject information, and committee review opinions.

3. Receive relevant continuing education and training including scientific research ethics, and continuously improve review capabilities. force.

5. Requirements for attendance at committee

meetings The Ethics Review Committee should formulate relevant requirements for attendance at committee meetings. **6.**

Training and continuing education requirements

(1) The ethics review committee should establish a training mechanism. All members (including chairman and deputy chairman), full-time (part-time) secretaries and office staff must have at least one session of relevant laws and regulations, departmental rules, ethical review knowledge and ethical review committee guidelines and operating procedures before performing their duties. Only those who have trained and obtained training certificates at or above the provincial level (including provincial level) can take up the position. Records of the training are maintained in the Ethics Review Committee office.

(2) Members shall regularly receive relevant continuing education and keep training records. All members must receive training on the update of the ethics review committee system, guidelines, and guidelines operating procedures. The Ethical Review Committee is responsible for regularly conducting ethical training for relevant personnel within medical and health institutions.

(3) Require the chairman, deputy chairman and members of the ethics review committee to participate

Add a variety of continuing education training (including online or offline), including relevant ethics courses, ethics review seminars, ethics reports and experience sharing and other academic activities as well as other higher-quality academic activities, of which Category I should be obtained every two years Credits must be no less than 5 points.

7. Ethical Review Committee Management

(1) The ethics review committee should make relevant provisions on the preservation, management, review and copying of archives in accordance with archives management standards to ensure the security and confidentiality of archives. The retention period of ethical review documents should be consistent with the regulations for different types of research.

(2) Medical institutions need to provide independent and adequate file protection for ethics committees. storage space to ensure the security and confidentiality of files.

(3) In order to continuously improve the quality of ethical review and improve the management and review system of the ethics review committee, the ethics review committee should promptly improve the problems discovered during the inspection and evaluation of work quality and keep relevant records.

(4) The ethics review committee should also establish corresponding institutional documents and operating guidelines Procedures may include but are not limited to:

1. Ethics review application guide; 2. Confidentiality measures for ethics review; 3. Selection system for independent consultants; 4. Management of conflicts of interest; 5. Training system; 6. Fund management system; 7. Subject consultation and complaints management system.

Chapter 3 Responsibilities and Powers of the Ethics Review Committee

1. Make a review decision The ethics review committee shall approve, disapprove, or revise the research project under review. Decisions on approval after modification, reexamination after modification, suspension or termination of research.

In order to meet the ethical requirements of subject protection, the committee exercises the power to approve or reject a certain Research project responsibilities and powers, and the right to request modifications to the research project. Due to accidental injuries or violations during the research project, we have the right to request the suspension or termination of an approved research project. Review amendments to the protocol and informed consent form, and review serious adverse events and protocol violations. **2.** Requirements for Informed Consent The right to make requests for the informed consent

consultation process. **3. Follow-up**

review requirements: Based on the possibility and degree of risk

occurrence of research risks, we have

the right to request that the approved

Conduct regular follow-up reviews of accurate research projects.

4. Others

In accordance with national regulations on hierarchical management, complete the approval of new biomedical technology clinical research projects of different risk levels and ensure filing and/or review by the institutional ethics review committee.

Chapter 4 Review Contents and Requirements of the Ethics Review Committee

1. Review content For

clinical research projects, ethical review mainly includes the following content: 1. Whether the

qualifications and experience of the researcher meet the requirements of clinical research; 2. Whether

the research protocol meets the requirements of scientific and ethical principles; 3. Subjects Are

the possible risks justified by the expected benefits of the study?

reason;

4. During the process of obtaining informed consent, information provided to subjects or their legal guardians

Whether the relevant information is complete and easy to understand, and whether the method for obtaining informed consent is appropriate;

5. Whether confidentiality measures have been taken to protect the subject's information and data;

6. Whether the guidelines for the inclusion and exclusion of subjects are appropriate and fair;

7. Whether the subjects are clearly informed of the rights they should enjoy, including that they can withdraw from the study at any time during the research process without reason, and will not be disadvantaged as a result. the right to fair treatment;

8. Whether the subject received reasonable compensation for participating in the research, such as In the event of injury or even death, whether the treatment and compensation measures given are appropriate;

9. Is there a dedicated person among the researchers who is responsible for handling the process of obtaining informed consent and the subject matter? Issues related to tester safety;

10. Are measures taken to minimize the risks that subjects may bear during the research? give;

11. Whether there is a conflict of interest between the researcher and the subject that may affect the researcher's professional judgment.

2. Review requirements (1)

Scientific value of research

The medical institution has conducted a sufficient professional review of the scientific nature of the proposed clinical study design, confirming that the study design is scientifically sound and is likely to produce valuable scientific information. Scientific review opinions should be recorded in the ethics review committee's documents. (2) Social value of research

1. In order to meet ethical requirements, all clinical research, including research on clinical case information, human tissue or sample data information remaining from clinical diagnosis and treatment, must have social value, including the quality of the scientific information intended to be generated by the clinical research, and Relevance to important clinical questions: whether it will help generate new clinical interventions or

Contribute to the evaluation of clinical interventions, help promote personal or public health, etc.

2. The key element in evaluating the social value of research is whether clinical research produces valuable scientific information that cannot be obtained by other means. For example, if the purpose of research is only to increase doctors' prescriptions related to research, it is a marketing behavior disguised as scientific research and cannot meet the requirements of the social value of clinical research. 3. The purpose of international

collaborative research should focus on solving the medical and health problems that need to be prioritized by the subject population, paying attention to whether the intervention measures produced by the research results can benefit the population in the country and region, and the accessibility of the research results.

(3) Subject protection 1.

Scientific value and social value are the fundamental reasons for conducting research, but researchers, research sponsors, and ethical review committees all have moral obligations to ensure that the rights of all research subjects are respected and protected.

2. The scientific and social value of research cannot serve as an ethical justification for unfair treatment of research subjects. Under no circumstances should the importance of increased knowledge in medical science and the health interests of future patients override the safety and health well-being of current subjects.

(4) Subject recruitment

1. Subjects should be recruited for scientific reasons rather than for social or economic reasons. Economic status, or the health vulnerability of desperate patients make recruitment easier.

2. The research subject population should include as many people as possible that reflect age, gender and ethnicity. diverse groups so that research findings can be generalized to all relevant populations. 3. Excluding vulnerable people from

subjects was once considered the most convenient way for them However, this protection method prevents vulnerable groups from enjoying research results and affects the diagnosis, prevention and treatment of diseases in these groups, thus leading to injustice to them.

just. Vulnerable subjects should be encouraged to participate in clinical research to correct these injustices.

4. When some or all of the recruited subjects are vulnerable groups susceptible to undue influence (such as children, people with intellectual disabilities and mental disorders, or desperate patients, etc.), additional protective measures need to be included in the research protocol to safeguard the rights and interests of these vulnerable

subjects. 5. The ethics review committee needs to review subject recruitment advertisements and recruitment letters. During the course of the research, the ethical review committee may also require necessary revisions to recruitment advertisements and recruitment letters.

6. As a general ethical principle, test subjects should not be burdened with validating clinical research costs associated with safety and efficacy. Institutions that choose to fund the development of clinical medicine should bear all costs incurred in verifying safety and efficacy.

(5) Informed Consent

Obtaining informed consent from subjects is a necessary condition for conducting research, but it is not sufficient. conditions, it is the researcher's responsibility to protect subjects from harm. 1.

Obtain written informed consent from the subjects

(1) In addition to the exemption clause of informed consent, the ethical review committee requires that the informed consent of the intended subjects or their legal guardians be obtained before the clinical research is carried out, and the informed consent must be filed with the

ethical review committee. (2) Informed consent should be expressed in a manner and in plain language that the subject or his/her legal guardian can understand. Informed consent is obtained when the subject or/and his/her legal guardian is not unduly influenced and has been fully considered. Got it. (3) It is not

allowed to use any reason in the informed consent form that may force the subject or his legal guardian to give up, or be inclined to give up any legal rights, nor is it allowed to use any reason that may make the researcher, sponsor, or research institution or related agencies are exempt from liability

(or language that implies a disclaimer).

(4) Informed consent must be obtained from the person in charge of clinical research or the researcher of the research project designated by him, and must be signed and marked by the subject himself or his legal guardian. date.

(5) In clinical research with agent consent, subjects must be strictly protected and efforts must be made to avoid risks that exceed the minimum risk due to the addition of non-therapeutic procedures (for research purposes).

(6) In the informed consent form, the researcher should inform the subjects that the research The way it turned out. When the research results cannot be provided to the subjects, this should also be explained to the subjects in the informed consent form.

(7) The informed consent form approved by the ethics review committee is considered the only formal consent document, and any informed consent document different from this version is not allowed to be used in the study.

(8) The informed consent document that has been approved by the ethics review committee is kept in the ethics review committee office.

2. Obtain oral informed consent from subjects. The

ethics review committee may allow obtaining oral informed consent from subjects under the following circumstances: agree:

(1) The possible risks to subjects in this clinical study do not exceed the minimum level. (2) When the subject is illiterate or blind, the contents of the informed consent form can be submitted orally to the subject or legal guardian, and any adult who has no interest in the subject or the researcher can sign as a witness. Demonstrate subject consent. Audio and video materials may also be retained as evidence. (3) The only link between the subject and the clinical study is the informed consent to be archived

documents, and the primary risk to subjects participating in research is the risk or harm that may result from the disclosure of sensitive information and privacy (including but not limited to surveys and interviews involving violence, rape, HIV patients, social and Behavioral research, etc.), the subject may be worried that signing the informed consent form will pose a threat to the privacy protection of the subject. In this case, the ethics review committee can approve the oral consent after discussion and evaluation, but the voice should be left Supporting documents such as documents serve as evidence of consent. Ethical review committees can still require researchers to provide participants with information about informed consent.

3. Post-informed consent

Certain special psychological and behavioral sociological studies cannot be conducted if the informed consent of the subjects is required. Ethical review boards may approve post hoc (after the study is completed) informed consent. The ethical review committee should evaluate the risks of the research, confirm that the risks of the research are no greater than the minimum risk, and that the subsequent informed consent can be understood and accepted by the subjects. 4. When the exemption from re-obtaining informed consent

meets the following necessary and sufficient

conditions, the ethics review committee may approve the exemption from re-obtaining informed consent from subjects:

(1) Clinical research requires minor modifications

to the informed consent form, otherwise the research will not be substantially will not be completed.

(2) The risks that subjects may suffer do not exceed the minimum level. (3) Modify the

content and procedures for obtaining informed consent, and waive the need to obtain it again

The informed consent of the subjects will not have a negative impact on the rights and interests of the subjects.

(4) Exemption from obtaining informed consent again does not mean exemption from the ethics review committee meeting's review.

5. Waiver of informed consent

The ethics review committee may approve the waiver of informed consent when the following necessary and sufficient conditions are met:

(1) The risks that subjects may suffer do not exceed the minimum level. (2) Exemption

from obtaining informed consent from subjects will not have a negative impact on the rights and interests of subjects. (3) Conduct research

using human body materials or data with identifiable information,

The subject cannot be found, and the research project does not involve personal privacy or commercial interests.

(4) The biological sample donor has signed an informed consent form and agrees to the donation

Samples and related information are available for all medical research.

(5) Exemption from obtaining informed consent does not mean exemption from review by the ethics review committee.

(6) Assessment of possible risks and benefits of research 1. If the purpose

of the research is to directly benefit individual subjects in diagnosis, treatment or prevention, the risks and benefits of the research should be determined through demonstration and other existing research methods. Compared with intervention methods, the benefits can be at least the same. The risks of such "beneficial" interventions need to be weighed and justified against the expected benefits to the individual subjects.

2. If the purpose of the research is not to directly benefit the subjects, then the risks to the individual subjects must be weighed and justified against the expected social benefits of the research (that is, the acquisition of generalizable medical knowledge). The risks posed by research must be reasonable in relation to the knowledge that may be gained. 3. For the sake of important scientific value, when

the risks that subjects may suffer are allowed to be slightly higher than the minimum risk, the risks should be strictly limited within a certain range, and the subjects shall not suffer serious or irreversible harm.

4. When research involves subjects who are incapacitated or have limited behavioral capacity, the scientific and ethical rationality of recruiting such subjects should be demonstrated. The risks of research that cannot directly benefit individual subjects must not be greater than the risks of conventional medical treatment. If a slightly increased risk is allowed, there must be a very strong scientific or medical justification and basis, and approval by an ethical review committee must be obtained.

5. When evaluating the risks and benefits of research, the ethics review committee only examines the risks and benefits that may arise from the research itself. 6. The data information obtained from

the research may be used in the future, and future applications can

The risks involved are not included in the risk assessment of this study.

7. During initial review and review, the subject's benefits should be assessed and documented as:

(1) There is no expected direct benefit to the individual subjects, but it is possible to obtain information about the disease of the subject group; (2) There is

no expected direct benefit to the individual subjects, but it is possible to obtain information based on the subject group. Studying diseases may have far-reaching social effects and the accumulation of scientific knowledge; (3)

Research includes direct benefits to individual subjects.

8. During the initial review and reexamination, the degree of risk faced by the subject should be assessed and recorded as: (1) A risk

that does not exceed the minimum; (2) A risk that is

slightly increased or higher than the minimum. (7) Protection of privacy and confidentiality

1. The ethical review committee needs to ensure that the research project has adequate measures to protect the subjects Privacy and maintaining the confidentiality of subjects' personal information;

2. When using subjects' personal health information for the purposes of subject's health needs, scientific research and major public interests, valid authorization is required.

3. Approval Guidelines

(1) The scientific nature of the research has been fully academically demonstrated, and its social value and the rights of the subjects have been fully respected and protected. After full discussion, the ethics review committee approves a research application with a legally valid vote (determined in accordance with the ethics review committee charter and relevant national regulations).

(2) The research projects applying for ethical review have obtained corresponding approvals in accordance with relevant national regulations. If applicable, include but are not limited to approval documents from the Office of Human Genetics, clinical trial approval documents from the State Food and Drug Administration, and approval documents from the Radiological or Biosafety Committee and other agencies.

(3) Research projects applying for ethical review have data and safety supervision (DSM) measures to ensure the safety of subjects. (4) Clinical research on new biomedical

technologies with different levels of risk must comply with relevant regulations promulgated by the state.

Chapter 5 Review Methods and Categories of the Ethical Review Committee

1. Ethical review methods (1) Meeting

review: Convene an ethics

review committee meeting for review, including but not limited to the initial review and review of the research protocol. **(2) Simplified Procedure Review** The chairman of the Ethics

Review Committee may designate one or

several members with relevant professional background and experience to conduct a simplified procedure review of the research plan. Eligible for simplified review:

1. Minor changes to the research protocol that have been approved by the ethics review committee and are within the validity period of the approval. A minor change is one that does not change the risk-benefit profile of the research.

A change that does not affect the wishes of the subjects in the study; a change that does not alter the scientific validity of the research design. Examples of minor changes include (but are not limited to) procedures to further reduce risk, additional laboratory testing to enhance subject safety, etc.

2. In multi-center clinical studies, participating units can recognize the decision of a single ethics review through a simplified review procedure. 3. When implementing

the simplified procedure review, the chairman (or designated member) of the ethics review committee receives and reviews the application materials. The simplified procedure can fulfill all the powers of an ethics review committee (except disapproval of the study). 4. If the decision on simplified review is to disapprove, or if it is considered

that it does not comply with the simplified review

If there are procedural conditions, the decision should be submitted to the ethics review

committee. 5. The simplified procedure review does not mean that the review guidelines are different, nor does it necessarily mean that the review process will be shortened in time (although due to the simplicity of the review procedure, the review time will usually be shorter). Summary procedure simply means that the procedure is exempted from meeting review.

6. The results of the simplified procedure review should be notified to all members of the ethics review committee.

(3) Review of research on emergency subjects

1. Even in emergency situations, clinical research using humans as subjects is not allowed without prior review and approval by the ethics review committee. 2. When emergency medical treatment involves

the use of an investigational drug, device, or biological agent, the patient cannot be considered a subject of the emergency clinical investigation. Such emergencies are medical and not research, and any data relating to this medical treatment will not be included in any reports on prospective research activities.

3. When emergency medical treatment involves the use of investigational drugs, devices, or biological agents,

Must meet the relevant regulations and requirements of our country's authoritative management departments.

(4) Emergency review The

urgency of conducting epidemic-related research during an outbreak poses a huge challenge to the review work of the ethics review committee. The ethics review committee should insist on conducting independent and impartial reviews of research projects based on the highest scientific and ethical standards to ensure the quality and timeliness of ethical reviews. Please see Appendix 8 for relevant requirements.

2. Ethical review categories: To

ensure that clinical research project ethics review applications comply with regulations and ethical issues are resolved For prompt consideration and processing, the Ethical Review Committee should conduct an initial review and review process.

(1) Initial review Initial

review refers to the researcher's first submission to the ethics committee before the study begins. submitted application for

review. **(2) Review**

Review includes reexamination, amendment review, follow-up review, serious adverse event review, Violation of protocol review, suspension and/or termination of research review, final review, etc.

1. The ethical review committee conducts follow-up reviews at a certain frequency based on the degree of research risk and possibility of occurrence for clinical studies that have been approved for

implementation. 2. In addition to the simplified procedure review for plans that meet the conditions for simplified procedure review, the ethics review committee requires a meeting review for the initial review of the research plan, and the review decision will be valid for a maximum period of no more than 12 months. Clinical studies longer than one year were reviewed until no more new data were generated from subjects.

3. During follow-up review, all previously approved or modified content must be compiled into the trial plan.

4. If the person in charge of the research project fails to submit relevant materials for follow-up review to the ethics review committee one month after the deadline, the committee may terminate the continuation of the trial. Restarting a terminated trial protocol requires a new trial protocol application to the review committee. 5. The secretary of the ethics review committee should prepare complete trial protocols,

follow-up review reports, ethics review records and other documents for the meeting review, so that they can be reviewed by the committee members during the meeting review.

6. Modify the approved trial protocol. If the project leader needs

to modify the approved research protocol during the trial, the revised protocol must be approved by the ethics review committee before it can be implemented in accordance with the revised protocol. Unless the requirements for simplified review are met, modifications to the trial protocol must be reviewed and approved by the ethics review committee meeting.

7. Review of application for termination of trial protocol

(1) The application for termination of the trial protocol submitted by the project leader must be reviewed by the ethics review committee meeting to ensure that the safety and welfare of the subjects will not be endangered by the termination of the trial.

(2) The termination of a trial protocol that violates ethical regulations shall be determined by the ethics review committee. proposed and reviewed at the meeting. 8. Review of

collaborative projects/multi-center collaborative research projects

(1) The review of international cooperation projects requires the ethics review of the international leading unit The review committee reviews and approves documents regardless of funding source.

(2) For domestic collaborative research projects, the trial protocols submitted to the ethics review committees of various medical institutions should be consistent, and the consent documents should be basically consistent. The Ethical Review Committee acknowledges that informed consent can vary slightly between institutions.

(3) In a multi-center research project, if the ethics review committee of the medical institution deems that verification of the project is necessary, the ethics review committee of the medical institution can independently make a review decision or propose modifications to the research project. You can also refer to the review opinions and decisions made by the ethical review committees of other institutions or accept the single review decision of the research project. 9. Review of serious adverse events or unexpected events

(1) The project leader is responsible for reporting serious adverse events that occur during the research process to the ethics review committee in a timely manner. (2) The ethics

review committee needs to make a judgment on whether the event is an unexpected event, its severity, and the relevance of the adverse impact on the research, and record its assessment.

(3) For unexpected serious adverse reactions, the ethics review committee may require the clinical study to be modified, suspended or terminated. The decision should be communicated to the person in charge of the research project, the person in charge of the institution, and the person in charge of the research management department in a timely manner, and the decision should be recorded and filed.

(4) For other events that occur during the implementation of the research, the research project leader must follow up

Submit a report to the ethics review committee during follow-up review.

Chapter Six: Materials and Preparations Required for Acceptance of Ethical Review

1. Responsibilities of the Research Project Leader

(1) The research project leader is responsible for research design, implementation and supervision. Before clinical research involving humans begins, the project leader is responsible for ensuring that informed consent has been obtained from the subjects and that the consent is voluntary after fully understanding the clinical research protocol.

(2) The project leader needs to submit the clinical research plan to the ethics review committee

and informed consent form (including informed process) and other relevant documents.

2. Documents that the research project leader needs to submit to the ethical review committee

(1) Documents submitted for initial review application, including but not limited to 1.

Complete research protocol. The

contents of the clinical research protocol include but are not limited to date, version number and page number.

Complete research plan, including project introduction, research objectives, research design and methods, inclusion and exclusion guidelines, protection measures for subjects (reasons for selection of research subjects, recruitment plan and procedures, description of the process of obtaining informed consent ; and measures to protect subject privacy and keep confidential subject information; plans for reasonable compensation for research subjects; plans for reporting adverse events). If applicable, it should also include data and safety monitoring plans, plans for the use and storage of biological samples, etc.

2. When the informed consent

document is appropriate, the ethics review committee may request a translation of the informed consent document.

(If the subject is a minority). The content of the informed consent document includes:

(1) Research purpose, research background and product introduction, as well as the expected duration of subjects' participation in the study; (2)

Description of the research process and the approximate number of recruited subjects;

(3) Foreseeable risks and affected persons A description of the discomfort or inconvenience that the test subject may suffer and an estimate of the likelihood of its occurrence. If appropriate, describe the prevention and mitigation measures taken and measures to address those risks or discomforts;

(4) A description of any possible benefits that subjects may expect from the study; (5) If possible,

appropriate alternative procedures or treatments that may be beneficial to subjects; (6) Concerns about subject privacy and

Measures to protect confidential information and who may have access

or obtain a description of the research record; (7) If

the research involves risks that may exceed the minimum risk limit, in the event that

In case of injury, a description of the medical treatment and compensation and/or compensation available to the subject;

(8) Answer the scientific questions involved in the research and the information of the research subjects.

Contact person for rights issues and their contact information;

(9) Explain that participation in the study is voluntary, and that subjects who refuse to participate in the study or withdraw from

participation in the study at any time will not be treated unfairly, will not affect the relationship between the subjects and clinicians and normal

medical treatment, and will not be affected. Any due health benefits will be lost as a result;

(10) When appropriate, the ethics review committee may require researchers to provide

Provide the following additional information:

ÿ Treatment or research procedures may have risks to the subjects (or to the embryo or baby, if the subject is a pregnant woman or a

woman who may become pregnant), and the risks are currently unforeseen. ÿThe researcher may terminate the prospective subject's participation

in the study

or terminate the study without the subject's consent.

ÿNew major discoveries during the research process may affect the continued participation of research subjects.

With willingness, newly discovered information will be provided to research subjects.

ÿ A statement on whether there is a potential conflict of interest for the researcher in the research plan, and

and a description and explanation of potential conflicts of interest.

3. The scientific review of the project passes the document. The

research project management department of the medical institution where the project leader works shall review the proposed application for ethics review.

Documents that pass the scientific review of the research project; 4. Researcher's

Manual (if any)

5. Other documents required by relevant national regulations

(2) Documents that need to be submitted to the ethics review committee for follow-up review

1. Follow-up review application;

2. Summary report of follow-up review, the content of which may include:

(1) A brief description of the progress and findings of the

study; (2) A summary of any changes to the study protocol since the previous review; (3) An

increase in the number of subjects, a summary of subjects withdrawing from the study; (4)

Adverse events and Involves any unintended consequences for the subject or other persons

a summary of the risks;

(5) Any complaints about research since the previous research ethics committee review

Report;

(6) Any relevant multi-center clinical trial reports; (7) Any reports from the

Data and Safety Monitoring Board (DSMB) (if applicable); (8) Literature review of any other relevant

information,

especially relevant to the study Literature review of risk information; (9) Adding any additional informed

consent content requirements; (10) Reasons

for continuing the study. (3) Documents that need to be submitted to the

ethics review committee when modifying the

research plan

1. A description of any modifications to the research protocol; 2.

A description of any impact that modifications to the research protocol will have on the research, regarding the subjects' access to

A description of acceptable risks and benefits;

3. Add additional informed consent requirements. (4)

Documents that need to be submitted to the ethics review committee when completing the project

The leader of the research project submits a project completion report to the ethics review committee. (5) Documents that need to be submitted to the ethical review committee when terminating the research. The person in charge of the research project submits an application to the ethical review committee for terminating the trial protocol.

When , you should submit:

1. A complete application to terminate the study; 2. A brief explanation of the reasons for termination; 3. The impact of terminating the study on subjects who have already received intervention treatment; 4. For subjects who are still being followed up in the study. Follow-up arrangements for candidates; 5. List of publications completed by the project during the period under review.

Chapter 7 Organization Review Meeting

1. The effective number of people at the meeting 1. The effective number of people at the meeting is that the committee members present at the meeting to participate in the review should reach more than half of the total number of members and include medical majors, non-medical majors, people independent of research/test units and people of different genders. The meeting is valid.

2. Members who participate in the meeting via video, if they have received all the information before the meeting Those members who have appropriate materials and participate actively and impartially in the discussion will be counted as effective members and allowed to participate in voting.

3. The effective number of people should include at least one senior clinical physician committee member with professional background. member.

2. Voting at the meeting 1. Every member participating in the review shall vote; 2. The meeting shall be held by more than 1/2 of the total number of members (except where there are special provisions) Opinions make decisions on the review plan;

3. Specially invited independent consultants are not a formal committee and do not participate in voting, but their professional Opinions are important for the committee to make the final decision; 4. Proxy voting is not allowed; 5. Members with substantial conflicts of interest will not participate in voting. **3. Meeting management** 1. Meeting time and schedule

The ethics review committee needs to schedule review meetings regularly. The schedule is arranged by the Ethical Review Committee Secretariat, and clinical research applicants and review committee members are notified in a timely manner.

2. The documents required for the review application must be accepted at least 25 working days before the meeting. The person in charge of the research project must submit the documents to the ethics review committee at least 25 working days before the meeting. Copies of materials and electronic text materials submitted to the Review Committee for review. (1) Materials required for initial review: ÿEthics review application form ÿComplete and detailed research plan and supporting documents ÿInformed consent documents (except those applying for exemption) ÿSupplementary materials (if applicable) (2) Tracking of long-term projects The review requires submission of a brief research progress report.

3. Distribution of documents

Documents for review are prepared, collated and distributed by the Committee Secretariat. At least 5 working days before the meeting, each committee member should receive meeting documents, including members who participate in the review meeting via video should receive electronic text files. Documents distributed before the meeting include:

(1) Meeting schedule (including time, location, review project list, review requirements, etc.);

(2) Minutes of previous meetings related to the items reviewed at this meeting; (3) Provide

a sufficiently detailed research plan to help members make decisions that comply with relevant regulations and management requirements. 4. Meeting

presiding procedures (1)

Confirm that the number of committee members present at the meeting reaches a valid number and announce

the start of the meeting. (2) Vote on the minutes of previous meetings

when necessary. (3) After the project leader leaves, the committee members discuss the research plan (long-term annual review/short-term review/amendment of the short-term plan or review of other plans). (4) Make a

review motion and vote. (5) Adjourn the meeting after all

agenda items have been reviewed and discussed. (6) The ethics review committee formally

notifies the project leader of the review decision. (7) Participating members, specially invited

independent consultants, committee staff, graduate students and visiting researchers who are allowed to participate in the meeting all need to respect the confidentiality of the review process and review results of the Ethics Review Committee, and sign relevant review items, Confidentiality Agreement for Subject Information and Related Matters. 5. Meeting resolutions

(1) The ethics review committee should have complete audio records. The secretary will record the meeting review content and promptly compile the meeting discussion summary and review decisions after the meeting to form meeting minutes. After the committee members attending the meeting have reviewed and found no objection, the chairman (or authorized person) will sign and file it.

(2) The secretary should formulate written ethics review opinions and clear review approval documents based on meeting minutes and voting results. The approval document shall be signed by the chairman (or authorized person) and stamped with the official seal of the Ethics Review Committee. (3)

The ethics review committee may make one of the following decisions on the submitted research plan:

1: Decisions of approval, approval after modification, reexamination after modification, disapproval, suspension or termination of research. Approval is valid for up to 12 months, and if the ethics review committee believes that the risk to subjects may be higher, more frequent follow-up reviews are necessary. The ethics review committee may request periodic follow-up reviews (with a period of less than 12 months) based on specific research. The review resolution and plan approval date should be recorded and filed.

ÿApproval

The ethics review committee can unconditionally approve an initial review research protocol and follow-up Traceability review plan.

The approval is valid for a maximum of 12 months, and research can begin immediately after approval/ Or proceed. ÿ The revised

approval ethics review

committee can conditionally approve a research protocol. When the modification opinions proposed by the Ethics Review Committee are accepted and responded to by the project leader, the approval decision will take effect.

ÿ Re-examination after

modification When the ethics review committee needs more substantive information about the research plan under review, the committee may make a decision to suspend the review until the committee receives new information and then reconvene the research plan to review it. ÿ The ethics review

committee can

vote against a research plan if it does not approve it. decision not to approve The project leader shall be promptly informed of the reasons for disapproval. The decision to disapprove can only be made during a review meeting, and the project leader should be given an opportunity to defend himself.

If the project leader disagrees with the ethics review committee's decision, he should Work with the committee to resolve issues during the debate.

ÿ Suspension or termination The

Research Ethics Review Committee may suspend or terminate the research project based on the progress of the research project. decision to stop research.

Except for the ethical review of multi-center projects, a protocol submitted to an ethics review committee for review can neither be submitted to another ethics review committee for review at the same time nor after that committee makes a review decision. **6. Meeting review records** (1) Record of the effective

number of people in the statutory

meeting ÿ The number of members participating in the

ethics review meeting shall not be less than 1/2 of the total number of members. The effective number of

people in the meeting. ÿThe list of participating committee members and their

professional fields should be recorded. ÿThe list of absent members and their

professional fields should be recorded. ÿThe list and institutions of other attendees, including independent consultants and visiting

scholars, should be recorded. (2) Voting

document records ÿ Voting can be recorded according to the following rules: total votes = #; number of approval votes = #; number of approval votes after modification = #; number of reexamination votes after modification = #; number of disapproval votes = #; number of avoidance votes = #.

ÿThe meeting should try to reach a consensus through full discussion and argumentation. When opinions differ, the opinions of the minority should be recorded separately rather than just the majority opinion.

ÿAny discussions and solutions to controversial opinions and ethical issues should be recorded. (3) Benefit/risk assessment record

The ethical review committee is required to make an assessment based on the degree of risk and likelihood of occurrence, as well as potential benefits, that the clinical research protocol may expose subjects to, and explain in the record that the decision to approve a certain research protocol is based on the evaluation of the protocol. , archive the record. ÿAdult subjects can participate in clinical

studies with risk levels that are: (a) no greater than the minimum risk; (b) moderately increased risk than the minimum risk (the ethical review committee will judge "moderate").

ÿAdult subjects can participate in clinical studies with benefit levels: (a) Unexpected

There is direct benefit to the subjects, but there may be benefits in the understanding of diseases related to the subject group;

(b) There is no expected direct benefit to the subjects, but there may be some benefit in the accumulation of scientific knowledge. Benefit society; (c) The clinical research includes direct benefits to the individual subjects.

3. Research in which children may participate: (a) Research may be approved only if it is shown that the research has the potential to lead to the acquisition of knowledge in the prevention or alleviation of serious problems affecting the health and well-being of children. (b) Research that does not exceed the minimum risk; (c) Research that moderately exceeds the minimum risk, but is expected to directly benefit the child subjects; (d) Research that moderately exceeds the minimum risk and has no expected benefit. Direct benefit to pediatric subjects, but may benefit the pediatric subject population. (4) Review resolutions and other records

Review minutes of meeting resolutions, as well as any relevant research protocols and informed consent forms

Details of changes should be recorded in the review document.

7. The decision of the Ethics Review Committee shall

be communicated. The Ethics Review Committee shall give a written review within 10 working days after the review. Opinions/approvals.

Chapter 8 Conflict of Interest Management Policy

1. Member selection

The person in charge of the scientific research management department or the person in charge of the clinical research department of the medical institution shall not Should serve as the chairman or deputy chairman of the ethics review committee.

2. Members who have

obvious and substantial conflicts of interest with the research project due to avoidance of voting cannot participate in the review of the research plan of the Ethics Review Committee. During the review, the chairman committee needs to ask whether all committee members are aware of the conflict of interest policy and ethical requirements, and whether there are committee members who need to declare conflicts of interest related to the research protocol under review, and the answers will be recorded. Committee members with clear and substantial conflicts of interest should refrain from participating in final discussions and votes on the research protocol. Matters of avoidance should be recorded and filed.

Chapter 9 Glossary

1. Confidentiality: Preventing proprietary information or personal information from being disclosed

Personal identity information is disclosed to persons who have no right to know.

2. Standard Operating Procedure (SOP): Detailed written operating instructions developed to ensure consistency of implementation and achieve a specific purpose. 3. Adverse Event: An adverse medical event that occurs after a patient or clinical

research subject receives a certain experimental intervention. Adverse events are trial-related when there is probable justification for the event.

4. Non-compliance/Violation: refers to all deviations from the trial protocol approved by the ethics review committee, and such deviations have not been approved by the ethics review committee.

The prior approval of the Ethics Review Committee is required, or the situation does not comply with/violate the regulations on the protection of human subjects and the requirements of the Ethics Review Committee.

5. Vulnerable Population: Relatively (or absolutely) people who are unable to safeguard their own interests, usually refers to those whose ability or freedom is restricted and unable to give consent or refuse consent, including children, who are disabled due to mental disorders People who are unable to give informed consent, etc.

6. Single Review: In multi-center clinical research, the ethics review committees of each research institution determine the ethical review of one ethics review committee through a certain collaboration mechanism.

7. Multicentre Clinical Trial (Multicentre Trial): following the same protocol, in Multiple trial centers, with multiple researchers responsible for implementing completed clinical trials.

8. Quorum: The number and qualification requirements of the ethics review committee members who must attend the meeting to review and decide on a trial, that is, the number of members and qualification requirements that should be present for a valid meeting.

9. Legal guardian (Guardian): refers to a person who serves as the guardian of a person without capacity for civil conduct or a person with limited capacity for civil conduct in accordance with the provisions of the law and performs guardianship duties. Those who serve as legal guardians must have guardianship capabilities. The determination of guardianship ability is mainly determined based on factors such as the guardian's physical health, economic conditions, and life contact with the ward. According to the provisions of the General Principles of Civil Law, legal guardians include legal guardians of minors and legal guardians of mentally ill persons.

(1) Legal guardians of minors include: ÿ parents; ÿ grandparents, other close relatives and friends; ÿ legal person organizations such as the parents' unit or the residents' committee, village committee or civil affairs department of their place of residence. The order of serving as legal guardians is determined by the distance of blood relationship and organizational relationship, with the order coming first.

The exclusion order is in the latter.

(2) Legal guardians of mentally ill patients include: ÿ spouse, parents, and adult children. ÿOther close relatives such as grandparents, maternal grandparents, brothers and sisters who have custody. ÿ Other close relatives and friends. ÿThe residents' committee and village committee of the unit or place of residence of the mentally ill person, and the local civil affairs department. Determining the guardian is also done in the order listed above.

10. Unexpected Adverse Event: The nature, severity or frequency of an adverse event is different from the expected risk described in the previous protocol or other relevant information (such as investigator's manual, drug instructions).

11. Medical Institution: After registration, the "Medical Institution" Practicing License" institution.

12. Institutional Ethical Review Board (Institutional Ethical Review Board): According to the National Health Commission (formerly the National Health and Family Planning Commission) officially released on October 12, 2016, the "Biomedicine Involving Humans" came into effect on December 1, 2016. The committee responsible for ethical review is stipulated in the Research Ethics Review Measures.

13. Suspected Unexpected Serious Adverse Reaction (SUSAR) refers to the nature and severity of clinical manifestations that exceed the investigator's manual of the experimental drug, the instructions for the marketed drug, or the product.
Suspicious and unexpected serious adverse reactions based on existing information such as product characteristics summary. 14. Clinical Trial: Refers to clinical intervention research, usually including new interventions (such as new drug clinical trials) or new methods or purposes of existing interventions. (such as expanded indications). 15. Clinical Research: Research involving human subjects, The purpose is to advance medical knowledge and often includes clinical observational studies and interventional studies.

16. Conflict of Interest: When a member of the ethics review committee has relevant interests in the clinical research project under review, it affects his/her ability to make a fair and independent decision on the research project from the perspective of protecting subjects. review. Conflicts of interest often arise when members of the ethics review committee have financial, material, institutional and social interests in the review project.

17. Disclosure of Conflict of Interest: A solemn statement, statement and explanation of whether a conflict of interest exists. "Affirmation" is different from "statement". "Statement" mostly refers to a formal document issued to publicly announce a position on a certain issue or event, while "affirmation" emphasizes statements and explanations.

18. Ethics Review Committee

Institutional Review Board): an independent organization composed of medical professionals, ethics experts, legal experts and non-medical personnel. Its responsibility is to verify whether clinical research protocols and attachments are ethical, and to provide public assurance to ensure the safety of subjects. Safety, health and rights are protected. The composition and all activities of this committee should not be interfered with or affected by clinical trial organizations and implementers.

19. Clinical Trial Registration: Standardized clinical trial

The trial should be registered on the clinical trial registration website and obtain a registration number before implementation;

20. Regional EC/IRB: According to the management regulations formulated by the provincial health department, the ethical review committee is established in a certain region and is entrusted to accept the ethical review of research projects of medical institutions.

21. Data and Safety Monitoring: refers to the review of research data obtained in ongoing research projects to ensure the safety and well-being of subjects during the research process, as well as the validity and scientific value of the research.

22. Data and Safety Monitoring

Measure): refers to the methods used to review data results, reported event data (including adverse reactions and unexpected problems), and whether the study complies with the research protocol to ensure the safety and well-being of research subjects during the research process.

23. Data and Safety Monitoring Board (Data and Safety Monitoring Board): A formal committee composed of independent experts who are neither study organizers nor investigators, responsible for reviewing the accumulation of one or more ongoing research projects (or multi-center studies) data, key efficacy endpoints, and prespecified data throughout the study. The committee is the only research oversight organization with continuous access to unblinded safety and efficacy data, and makes recommendations to continue, modify, or terminate the study through an assessment of risks and benefits. It can have the power to request additional analysis and can schedule special meetings to review the data.

24. Research Participant: Individuals or groups of people participating in biomedical research, which can be used as the experimental group, control group, or observation group. Generally include healthy volunteers, voluntary participants not directly related to the trial target population, or from the diseased population targeted by the trial drug.

25. Vulnerability of subjects: Vulnerability can include (but is not limited to) economic vulnerability, institutional vulnerability, cognitive vulnerability, social vulnerability, medical vulnerability, and compliance vulnerability. (1) Economic vulnerability

(Economic Vulnerability): refers to the disadvantageous position of subjects in the distribution of social goods and services (such as income, housing or medical care), which may lead to improper inducement of research benefits and/or compensation. participation in research, thereby threatening their autonomy of choice and the risk of exploitation.

(2) Institutional Vulnerability: The subject suffers

Participate in research under the official authority of others. Such as criminals, soldiers, students.

(3) Cognitive Vulnerability: The subject is unable to fully

Make a decision whether to participate in the study after carefully understanding the information and thinking carefully.

(4) Social Vulnerability: A social group that is usually despised and discriminated against. The interests, welfare and contributions of its members to society are often despised or ignored. Socially vulnerable people also tend to be economically vulnerable.

(5) Medical Vulnerability: Refers to subjects who suffer from serious diseases and do not have satisfactory treatment according to the guidelines (such as patients with cancer metastasis, patients with rare diseases), because they or their doctors may think that it is best to prepare for research intervention. therapy and participate in research.

(6) Compliance Vulnerability: Different from institutional vulnerability, compliance vulnerability refers to subjects' submission to unofficial authority constructed by society, such as inequalities based on gender, race, or class, and differences between doctors and patients. Inequalities in power and knowledge, or of a more subjective nature, such as parents often complying with the wishes of their adult children. 26. Subject recruitment (Recruit): It is the

process of obtaining valid informed consent from potential research subjects (participants) or the subject's legal guardian to conduct relevant experiments. All clinical trials involving human research subjects should have obtained the approval of the ethical review committee before the recruitment of subjects can begin. 27. Protocol Amendment: To the trial protocol and related

Written modifications or clarifications to other documents and information implemented by the trial organization.

28. Research: Biomedical research involving humans includes the following activities: (1) Using modern

physics, chemistry, biology, traditional Chinese medicine, psychology and other methods to study human physiology, psychological behavior, pathological phenomena, and disease causes Activities to conduct research on the mechanisms of disease, as well as prevention, diagnosis, treatment and rehabilitation of diseases;

(2) Experimental research on new medical technologies or new medical products on human bodies Activity;

(3) Activities that use epidemiological, sociological, psychological and other methods to collect, record, use, report or store human samples, medical records, behavioral and other scientific research data.

29. Serious Adverse Event: An event occurs during clinical research that requires hospitalization, prolongs hospitalization, causes disability, affects work ability, threatens life or death, causes congenital malformations, etc.

30. Unexpected Serious Adverse Event: refers to any serious adverse event whose specificity or severity is different from that of the current study

The risk information provided in the operator's manual is inconsistent.

31. Informed Consent: After informing the subjects of all aspects of a study, the process of the subjects voluntarily confirming their agreement to participate in the clinical study must be signed and dated. Documentation.

32. Informed Consent Form: It is a document proving that each subject expresses his or her voluntary participation in a clinical study. The researcher must explain to the subjects the nature, purpose, possible benefits and risks of the research, other available treatment methods, and the rights and obligations of subjects in compliance with the Declaration of Helsinki, etc., so that the subjects can fully understand express their consent.

33. Therapeutic Misconception: This kind of research (including experiments) involving people is conceptually and practically different from treatment. Researchers conduct research in the same way as clinical treatment. Patients participating in clinical research often The misconception that you are receiving clinical treatment is called "treatment misunderstanding." Therapeutic misunderstandings do not satisfy ethical requirements regarding research and must be prevented.

34. Minimal Risk: The guideline for minimum risk is no higher than the harm faced in daily life, or the harm faced during routine physical or psychological examinations/tests.

Part 3 Supplementary Provisions

Appendix 1 Ethical Review of Drug/Medical Device Clinical Trials

1. General

Principles (1) In order to strengthen the management, guidance and supervision of ethical review of drug/medical device clinical trials, standardize the ethical review of drug clinical trials by the Ethics Review Committee, and ensure that drug/medical device clinical trials comply with scientific and ethical requirements, In accordance with the "Measures for Ethical Review of Biomedical Research Involving Humans", "Guiding Principles for Ethical Review of Drug Clinical Trials", "Declaration of Helsinki", "International Ethical Guidelines for Health-related Research Involving Humans", "Good Clinical Practice for Drugs" and "Clinical Trials of Medical Devices" "Good Clinical Practice" and "International Conference on Harmonization of Technical Regulations for the Registration of Pharmaceuticals for Human Use Good Clinical Practice" (ICH-GCP) have formulated this appendix.

(2) This guideline applies to drug/medical device clinical trials and other clinical trials carried out for registration purposes, including clinical trials of in vitro diagnostic reagents and formula foods for special medical purposes, etc.

2. Organization and Management of the Ethics Review Committee

The ethics review committee should be composed of people with multidisciplinary backgrounds. When reviewing phase I clinical trials of new drugs, if there is a lack of clinical pharmacology experts or preclinical research experts among the committee members, relevant experts can be invited when necessary. Assist in the review as an independent consultant. When medical device projects involve materials, electronics, machinery and other professional fields, experts in related fields can also be invited as independent consultants if necessary.

3. Documents such as institutional documents, guidelines,

operating procedures and ethics review application guidelines of the ethics review committee should clearly state the purpose of

Special requirements for clinical trials of new drugs/medical devices, including but not limited to: Food and Drug Administration opinions/approvals/acceptance notices or implied permission announcements for conducting clinical trials, sponsor qualifications, production qualifications of experimental drugs/medical devices, inspection reports, Investigator's handbook or summary of drug/medical device preliminary studies, materials for recruiting subjects, etc. **4. Ethical review**

(1) The ethical review of drugs/medical devices pays special attention to the rationality and fairness of the selection of test subjects, and the mechanism of action and potential risks of the drugs/medical devices should be fully considered to protect the rights and interests of the subjects. Healthy volunteers can be selected as subjects in phase I clinical trials, and patients with target indications should be selected in phase II and III clinical trials.

Patients may be considered as subjects in phase I clinical trials when the following conditions exist:

1. The target of action only exists in the patient;

2. Pharmacokinetic data obtained from healthy volunteers cannot be extrapolated to the target at all. Indicated patients;

3. Healthy volunteers cannot tolerate the adverse reactions of treatment. If you need to select special groups, such as children, the elderly, pregnant women, patients or other There should be reasonable reasons for conducting research on other vulnerable groups and other vulnerable groups, and corresponding safeguards should be taken. (2) Ethical review pays special attention to conflicts of interest between researchers and sponsors, contract research organizations and other research participants. (3) Clinical trials of drugs/medical devices, especially first human trials of new drugs, In view of the limited understanding of the trial product, the scientific and ethical rationality of the protocol should be reviewed based on full consideration of the mechanism of action, preclinical research results, research results of known similar products at home and abroad, risk control measures, etc.

(4) When reviewing informed consent forms for drug/medical device clinical trials, focus should be placed on:

1. Introduce precautions for using research products; 2. Expected

risks and possible unknown risks of research drugs/devices/inspection items; 3. Drugs/devices/inspection items provided free

of charge by the sponsor; 4. Possibility of subjects participating in the trial Subsidy

received; 5. Measures to be taken after the injury occurs; 6. Privacy

protection measures (except for supervisors, auditors,

ethics committees and supervision departments)

The door can access the subject's medical records according to the corresponding

authority); 7. Processing of the subject's biological samples, etc.

(5) The ethics committee needs to pay attention to the subject recruitment procedures for drug/medical device clinical trials, establish relevant systems or operating guidelines, and review the materials for recruiting subjects.

(6) The ethics committee should formulate a follow-up plan for drug/medical device clinical trials.

Special requirements for review, the time limit for follow-up review can be shortened for the first clinical trial of a new drug, and regular follow-up review can be added at key nodes of adaptive design/phased clinical trials. (7) The ethics committee should formulate special

requirements for the review of safety events in drug/medical device clinical trials, paying special attention to suspected unexpected serious adverse reactions (SUSAR) in clinical trials of new drugs. (8) Ethics of suspension/early termination of clinical trials with patients as subjects

The committee should be concerned about the subsequent management of subjects still receiving investigational treatment.

5. Ethical review of multi-center clinical trials In multi-center

clinical trials, each participating center should conduct

The actual implementation situation and fully assess the feasibility, especially the risk control capabilities.

Appendix 2 Ethical Review of Genetics and Reproductive Medicine Research

1. General

principles are to regulate research related to human assisted reproductive technology, better protect subjects involved in genetics and reproductive medicine research, and other clinical research involving the collection of genetic data, according to the "Measures for the Ethical Review of Biomedical Research Involving Humans" (National Health and Family Planning Commission Order No. 11 in 2016), "Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans", etc., formulated this supplementary rules. This guideline is applicable to clinical research

in genetics and reproductive medicine. Ethical review by genetics research and reproductive medicine research ethics review committees should follow generally accepted ethical principles and relevant legal norms.

2. Key points for ethical review of clinical research on assisted reproductive technology

The natural human reproductive process consists of sexual intercourse, fertilization in the fallopian tubes, implantation of the fertilized egg into the uterus, Intrauterine pregnancy consists of other steps. Assisted reproductive technology refers to means that replace one or all steps of the above-mentioned natural reproductive process, mainly including: artificial insemination, in vitro fertilization, embryo transfer, egg/sperm and embryo cryopreservation, gamete fallopian tube transplantation, surrogate mother, single sperm egg Intracytoplasmic microinjection, preimplantation genetic diagnosis, assisted reproduction, asexual reproduction or human reproductive cloning, etc. Assisted reproduction technology mainly solves the problem of infertility. During its development, it is also used to solve the problem of preventing birth defects. (1) For research involving human assisted reproductive technology, the subjects are all patients who have received assisted reproductive

technology. Their treatment with assisted reproductive technology complies with relevant national laws and regulations and relevant technical specifications, and they have signed a valid agreement to accept assisted reproductive technology. Informed consent form.

(2) Since research interventions usually occur before or in early pregnancy, special attention is required.

Pay attention to the health and interests of future generations. If necessary, health follow-up during pregnancy and after the birth of the offspring should be included in the research plan. Subjects and spouses must have full civil capacity and be fully aware of the risks of the research, including risks to mothers and offspring. Both spouses signed the study informed consent

form. (3) For clinical research using pregnant women as subjects, the purpose of the research must be to obtain knowledge related to the health of pregnant women or fetuses. If the subject of the study is intrauterine fetuses, the risks of the study should be no greater than the minimum risk and the knowledge gained cannot be obtained through other subjects.

(4) For clinical research using pregnant women as subjects, the safety and effectiveness of the research intervention has been verified in animal experiments or non-pregnant people. If necessary, the research plan should include health follow-up during pregnancy and after the birth of the offspring. Pregnant women and their spouses must have full civil capacity and be fully informed of the risks associated with the research, especially the risks that the fetus may bear. Pregnant women and their spouses have the

right to decide when to terminate the pregnancy. **3. Key**

points of ethical review of clinical genetics research From the time of fertilization to birth, human beings develop and grow according to genetically determined procedures and under the influence of certain natural and social environments. Life sciences and biotechnology based on genetic research will more effectively predict, diagnose, treat and prevent diseases, improve health levels, improve quality of life, and extend healthy lifespan. At the same time, they will also cause a series of ethical, legal and social issues. question. The ethical, legal and social issues involved in genetic reproductive research are more complex and acute. Ethical review of clinical research involving genetics requires sensitivity to relevant issues in this field and ensuring the conduct of clinical research that is responsible for subjects, future generations, and even the entire

human society. (1) Legal

compliance in genetics research, including genetic disease diagnosis, genetic disease screening, and genetic collection

In exploratory research on genetic information, the collection, management and use of genetic information must comply with existing national laws and regulations, and genetic data can only be used to promote human health and well-being. (2) Informed consent 1. Subjects'

opinions on whether to undergo

genetic examination related to the purpose of the research and whether

Provision of genetic data for research should be fully informed and voluntary.

2. Subjects should be informed in detail about the purpose of collecting genetic data, collection methods (including invasive or non-invasive methods), data processing (anonymization), data use and data storage, etc. The data shall not be used beyond the scope informed by informed consent.

3. If it is necessary to use the remaining specimens or genetic data for other purposes,

Subject consent must again be obtained and approved by the ethical review board.

(3) Information Sharing: De-

identified genetic data can be freely shared among researchers. (4) Privacy protection

1. The human genome is part of the common heritage of mankind. Original genetic sequence data

It should be shared by all humans, but individuals have the right to genetic privacy regarding their own genetic information.

2. The results of genetic examinations related to clinical research shall not be released without the authorization of the subjects. Inform third parties.

3. Notification of unexpected discoveries. If there are unexpected findings as a result of clinical research, and the findings may be related to risks to the life and health of other members of the subject's family. It should be ethically permitted or even obligatory for researchers and medical staff to disclose relevant information to avoid harm, but it must be done through legitimate channels and to avoid exposing the subjects' privacy.

4. If there are unexpected findings in the research results, the research methods are reliable and accurate, and the risk of illness is

The risk is currently preventable and controllable, and subjects should be advised to receive clinical

diagnosis and treatment. 5. When the research accidentally discovers that the subject is a proband with a serious genetic disease, the risk of the disease is very high in the family, and there are clinical intervention methods, the researcher should recommend and encourage the subject to disclose the information to relevant relatives and receive clinical diagnosis and

treatment in a timely manner. 6. When unable to convince subjects to disclose genetic information to relevant family members, researchers This information can be disclosed, but the following conditions should be met: (1)

The potential harm is serious; (2) If not informed, the

probability of harm to family members is high, and the harm may be effectively avoided by informing; (3) The information should only be disclosed to avoid

Information necessary to harm. (5) Prenatal diagnostic research 1. Prenatal genetic disease

diagnostic research must use currently

recognized and reliable methods to conduct genetic testing, clearly inform the subjects of the purpose of diagnosis, the reliability of the results and possible consequences, and the subjects must be autonomous Decide whether to get tested.

2. Research on diagnostic methods should also conduct self-control studies using gold standard methods.

The results of the gold standard method test will be informed to the subjects and their spouses. (6) Protection

of regional groups

Genetic disease screening is a test of population susceptibility to genetic diseases for which effective prevention and treatment measures are available. Test results may relate to a specific region, ethnicity or race. In addition to obtaining informed consent from individuals, research needs to pay attention to differences in culture, society, and values, and pay attention to the protection of specific groups of people. Genetic information must be strictly kept and kept confidential, including coding and de-identification, and personnel with access to genetic data must be restricted. When data is published, adverse effects on specific geographical groups must be fully considered.

(7) Genetic counseling

1. Subjects should be provided with professional genetic counseling, especially for genetic diseases of high severity. 2. The subject couple

has the right to make reproductive decisions about the fetus that may be affected.

3. There should be follow-up recommendations for children with birth

defects. (8) Declaration and Management of

Conflicts of Interest Genetic information is highly individualized and has lifelong implications for individuals and families. information. The impact of genetic information testing results on patients' lives will remain with them throughout their lives, and even the diagnosis of underlying disease may cause stigma or discrimination. In genetics-related research, researchers, sponsoring companies, and institutions that conduct genetic testing must declare conflicts of interest and submit them to detailed review by the ethical review committee.

Appendix 3 Ethical Review of Psychiatric Clinical Research

1. General The

problem of mental disorders has had a profound impact on human society. Mental disorders not only have a profound negative impact on the quality of life of the patients themselves, but also cause the public to pay deep attention to mental illnesses. In clinical medicine, no discipline is as full of intense controversy as psychiatry, from basic concepts to disease classification, from diagnostic guidelines to treatment guidelines and even procedures. These debates not only affect the development trend and clinical practice of modern psychiatry, but also undoubtedly affect clinical research in psychiatry.

People with mental disorders are a vulnerable group among research subjects and are often unable to effectively safeguard their rights and interests. Their "vulnerabilities" come from multiple sources, including cognitive deficiencies, compliance deficiencies, and medical specialties. In clinical research, ethical concerns arise from the vulnerability of subjects who may be recruited into research in an ethically inappropriate manner and placed at undue risk.

This appendix applies to some issues that require special attention in the ethical review of psychiatric clinical research. Note the issue. This guideline is formulated in accordance with the Mental Health Law of the People's Republic of China "Shanghai Mental Health Regulations", "Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans", "Measures for Ethical Review of Biomedical Research Involving Humans", "Regulations on the Management of Human Genetic Resources", "Guiding Principles for Ethical Review of Drug Clinical Trials", and the world Declaration and Perspectives on the Rights and Legal Protection of Persons with Mental Illness of the Psychiatric Association (WPA) (1989), "Principles for the Protection of Persons with Mental Illness and Improvement of Mental Health Care" promulgated by the United Nations General Assembly (United Nations General Assembly Resolution 46/119, 1991) , and the World Health Organization (WHO) Mental Health Resource Manual: Human Rights and Legislation (2005) and other internationally accepted ethical principles.

2. Key points of ethical review

(1) Clinical research design 1. When

patients with mental disorders participate in clinical research as subjects, the knowledge gained from the clinical research must be beneficial to the people with mental disorders themselves, that is, it must be able to solve the medical problems that the people with mental disorders need to be solved first.

2. Vulnerable subjects with mental disorders should not be subjected to research that only benefits other populations but does not benefit the subject population now or in the future. 3. When the

research content involves the inevitable psychological trauma experience of the subjects, it should Psychological counseling services are designed in advance.

4. Minimize the risks that the research process may cause to subjects with mental disorders.

5. It is prohibited to conduct experiments on patients with mental disorders that are not related to the treatment of their mental disorders. Clinical care.

(2) Selection of subjects 1. Only when

other subjects cannot replace patients with mental disorders as subjects, you can choose to recruit patients with mental disorders as research subjects.

2. Only when patients with milder disease severity are not suitable as subjects, can patients with more severe mental disorders be selected as research subjects to participate in clinical research.

(3) Valid informed consent

1. It should be noted that when patients with mental disorders serve as research subjects, their ability to provide informed consent may be subject to dynamic changes. A dynamic approach to obtaining informed consent should be adopted for such subjects, and this should be included in the research protocol. Be clear and increase the frequency of informed consent if necessary.

2. Avoid tempting or disguised forcing patients with mental disorders to participate in clinical research, and be clear about Informed that not participating in the study would not have any negative impact on their normal medical care.

3. When obtaining informed consent from candidate subjects for clinical research, special attention should be paid to avoiding Avoid "treatment misunderstandings".

4. When the subject's ability to give informed consent may be changing dynamically, and when the subject loses or partially loses the ability to give informed consent, the consent of the subject's legal guardian must be obtained. Research may only begin or continue with the consent of the agent.

5. For subjects whose ability to give informed consent is partially impaired, based on the subject's ability to express their wishes, while obtaining the consent of their legal guardian, the subject should also be given the opportunity to agree or disagree with participating in clinical research. , and respect the subject's own consent or disapproval.

6. When the research subject is a long-term hospitalization patient in a mental hospital, he or she may have Students and researchers are dependent or susceptible to influence, and it is often "difficult for subjects to say no" to participate in research. The ethics review committee should pay particular attention to the purpose of the study and whether the risks and benefits of participating in the study are reasonable.

(4) Subject privacy protection

1. When it comes to publishing sensitive research results, it is especially necessary to respect the wishes of the subjects themselves and their stakeholders (including their relatives). 2. When

publishing statistical data, it may affect society because it involves information such as regional communities. Risks of stigmatization or discrimination should also be given special attention.

Appendix 4 Ethical Review of Clinical Research in Public Health Field

1. General

Principles The goal of public health is to understand the conditions and causes of poor health and good health in groups, and to seek an excellent environment that can enable people to maintain health. The purpose of its work is to monitor and evaluate the health status of populations and develop strategies and interventions. The goal of public health is group health, which is a collective action achieved through government or public institutions.

Research in the field of public health is generally any social scientific, biomedical, or epidemiological activity aimed at the systematic collection or analysis of data for the purpose of producing benefits primarily to communities other than those at risk of participation. Public health agencies collect and analyze identifiable health data to generate knowledge that can be generalized to prevent disease or promote health.

The ethical review of public health research projects should include experts in the field of public health and epidemiology experts. If the members of the ethics review committee do not include experts in the field of the project being reviewed, experts should be specially invited to participate in the ethical review. When research is designed to target sensitive communities and populations, consultation with representatives of the field or community should be sought when necessary.

2. Key points of ethical review

(1) The distinction between public health practice and public health

research 1. Public health

practice The practical activities of public health include the extensive collection and analysis of identifiable health data from multiple sources (such as demographic and health surveys) to implement a series of public health Health activities, including surveillance, epidemiological research, and evaluation and surveillance. The purpose of these surveys is to guide policy rather than generate new knowledge. Although they often include some research questions, these basic public health activities belong to public health practice. A distinction should be made between public health practice activities and public health research activities. Practice and Research

The differences not only have different operational consequences (reflected in how the intervention under study is designed and implemented in order to draw valid conclusions), but also have different ethical implications.

Characteristics of public health practice include:

(1) Special authorization by law and corresponding government obligations to engage in activities to protect public health; (2)

Directly implemented or supervised by public health agencies and responsible to the public; (3) Can

legally enable people who do not voluntarily participate or fail to participate Participants who have expressed

informed consent; (4) Respect the dignity and rights of individuals and obtain public health ethics and mutual assistance principles; support.

2. Public health research

The purpose of public health research is to generate new knowledge, and the subjects include the entire community or crowd. In public health research, subjects are exposed to manipulation, intervention, observation, or other direct interaction with researchers, exposed to changes in the environment, or through the collection, preparation, or use of biologically identifiable individuals by researchers. Materials, medical or other records.

For example, when the purpose of research is to test the effects of a new intervention, such as a drug or vaccine, the main difference between research and therapy is that treatment is performed to benefit a specific patient, whereas research is performed to gain new scientific knowledge. For example, a public health agency conducts a double-blind controlled study to evaluate the effectiveness of a new vaccine in a randomly selected population. The hypotheses, methods, and purposes underlying this research support the classification of this activity as research. Regarding ethical review requirements for research, the research design adopts a series of protective measures (such as individual informed consent when no exemption exists) and procedures to protect the health, safety, and autonomy

of human subjects. Subjects of public health research may include healthy volunteers or whole

a community or group of people.

3. The distinction between public health research and public health practice

It is important to distinguish between public health practice and research, and public health research needs to adhere to ethical review procedures. Depending on the nature of the activity, whether it is public health practice or public health research, whether the individual is required to authorize in writing the disclosure of identifiable health information to public health practitioners, and the researcher's access to such identifiable health information, including specimens and data) are different. The ethics of obtaining identifiable health information for research purposes are higher and therefore the requirements for obtaining this information are more stringent. Key to distinction:

(1) Purpose of the activity

Public health research is the pursuit of gaining generalizable knowledge about public health interventions. Public health practices are designed to protect the health of target populations in specific contexts. (2) Method

used

Public health research methods have not been proven to be safe and effective;
Hygiene practices use methods that have been tested and evidenced to be safe and effective, and the activity is the application of methods that have been proven safe and effective.

In some cases, public health practice and public health research are combined and difficult to distinguish clearly. In this case, the distinction may not be most important. What is more important is how the ethics committee determines the ethical issues and considers them. (2) Research design In public health research, research design should pay attention to compliance with general

ethical principles. In addition,

attention should be paid to the cultural context of the research community, health inequalities and vulnerable groups in the population, and the possibility of benefiting from the research results. and the importance of sex.

1. Research should be based on the social, cultural, political and economic conditions of the study location and community.

be sensitive to the context; 2. The

research design should avoid inappropriate utilization of the subject areas and populations; 3. The

research should help enhance the capacity of the subject community to improve the health system and reduce

Reduce health inequalities.

(3) Assessment of risks and harm

Public health research may cause other types of harm than harm to the body. These harms may be more severe

than potential physical harm to subjects associated with clinical research and include (but are not limited to):

1. Social behavioral research that explores sensitive information about subject behavior can make subjects

The tester's actions or answers are known to others and may cause social or psychological harm.

2. Conduct research before conducting large-scale clinical trials. Although formative research is often

Harmless, but may cause harm to or embarrass the community.

(4) Observational epidemiological research

plays a major role in public health research. Typically two types of epidemiological studies are used: observational

studies (descriptive, cohort, controlled and cross-sectional); interventional or experimental studies. Most epidemiological

(descriptive, cross-sectional, cohort or cohort) studies are observational only and do not involve preventive or therapeutic

interventions. 1. Confidentiality of data As ethical issues in research receive increasing attention, the understanding of

harm (potential

harm to subjects)

continues to deepen, and the privacy protection of subjects also attracts more and more attention. All All this

has important implications for observational epidemiological studies.

Different types of data have different identity traceability:

(1) Anonymous data: The data collected has no identifiers and has never been associated with someone Connect personally. For example, questionnaires returned by mail do not have names and addresses.

(2) Anonymized data: Previously identifiable data has been de-identified; any information that can be linked to a specific individual (such as ID number, credit card number, or even mobile phone serial number) has been eliminated, and third parties also process the information. It is impossible to reconstruct this information. (3) Pseudonymous data: data records

do not contain clear identification, although there are clear

identifier, but cannot be used to directly link the information to a specific individual. This protects personal information and data from disclosure, as such identifiers cannot be converted into unambiguous identification. (4) Clear personal data: This is the information that is easiest to

trace back to an individual,

Because such data records contain clearly identifiable information. 2. Research

Risks and Privacy Protection A person's

information can be leaked intentionally or unintentionally, causing harm to subjects. Some information is particularly likely to cause harm, may cause social stigmatization, discrimination, and damage to mental and social adaptability.

The leakage of subject privacy may become the biggest risk of observational research, and the protection of data Confidentiality has become the most concerning

issue. (1) Protection of genetic data

Genetic data is difficult to anonymize because, at least in theory, it can be combined with

Another biological sample that has genetic information and identifiers linked to it should have more protection measures for genetic data. (2) Data identifying identity

Some research cannot be done with anonymous data, especially if researchers need identifiers to

One set of records is linked to another, and although data can be anonymized at the end of the study, there is always a risk of information being compromised during the study. It should not therefore be assumed that the risks of participating in research can necessarily be eliminated. It is important to assess not only the likelihood that personally identifiable information obtained or generated during research could be inappropriately disclosed, but also the likelihood and extent of harm that would actually occur if disclosed.

(3) Deductive identification

In some studies, although identifying information (such as names) can be removed from the data or samples, the remaining data can still point to a certain person or persons, that is, the subject can be identified through deduction. For example, if there is a data set involving people in a specific town or urban area, people can identify who this person is by inferring the subject's gender, age, race, occupation, and neighborhood information.

(4) Community Harm

Sometimes research reports can also cause harm to the community. When the unit of study is a community, people are vulnerable to harm if published research results allow them to identify that community and the results paint that community or community in a negative light. For example, in the HapMap study, although there is no personal identification of the samples, it is known that these samples come from Beijing, China, Tokyo, Japan, or Nigeria.

(5) Privacy protection in big data processing

More and more public health information is processed with big data technology. In the era of big data, the loss of privacy is more likely to occur. Therefore, in observational epidemiological studies, both researchers and ethical reviewers face more difficult challenges regarding subject privacy and data protection.

Appendix 5 Ethical Review of Clinical Research of Traditional Chinese Medicine

1. General principles

Clinical research in traditional Chinese medicine is completely consistent with the basic ethical principles followed in clinical research in modern Western medicine. According to the characteristics of clinical research of traditional Chinese medicine, in order to further standardize the construction of the ethics review committee for clinical research of traditional Chinese medicine and strengthen the protection of subjects in clinical research of traditional Chinese medicine, these supplementary rules are specially formulated. This supplement is a supplement to the "Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans" and is a supplement to the basic guidelines.

This supplement is based on the "Traditional Chinese Medicine Law of the People's Republic of China", "Ethical Review and Management Standards for Clinical Research of Traditional Chinese Medicine", "Supplementary Provisions for the Registration and Management of Traditional Chinese Medicine", "General Principles for Clinical Research of New Traditional Chinese Medicines" and "Ethical Review System for Biomedical Research Involving Humans" Requirements" and other regulations and guidelines are formulated.

This Supplementary Provisions applies to medical and health institutions that carry out clinical research on traditional Chinese medicine. **2. Organization and management**

(1) Ethical review committee members and independent consultants. Medical and health institutions that conduct relatively intensive clinical research on traditional Chinese medicine must select an appropriate number of members with relevant professional backgrounds when establishing an ethics review committee. If the ethics review committee of a comprehensive medical and health institution that rarely conducts such research does not have a member with a relevant professional background, it should hire an independent consultant who is qualified for consulting work when reviewing such research projects, and the independent consultant can provide objective and impartial information on its scientific nature. advisory opinions.

3. Ethical review (1) Review of research protocols

1. The mainstream systems of traditional Chinese medicine and modern Western medicine belong to two different medical paradigms. Science, the two have different interpretations of medical theory, concepts of diseases, and application of methodologies. In the evaluation of the design of clinical research projects of traditional Chinese medicine, its characteristics should be fully considered.

On the basis of fully ensuring the safety of subjects, we should be inclusive and strive to explore.

2. Clinical research on traditional Chinese medicine should be guided by traditional Chinese medicine theory and use traditional Chinese medicine technology methods, and comply with the relevant regulatory requirements formulated by the national competent authorities of the traditional Chinese medicine industry.

3. Clinical research on traditional Chinese medicine should comply with its recognized theoretical principles and methods, and respect accumulated clinical experience for many years. Long-term traditional medicine practice and experience can be used as early evidence for clinical research on traditional Chinese medicine.

4. Research on traditional Chinese medicines with a clinical application basis, which are derived from "compound preparations of traditional Chinese medicines based on ancient classic prescriptions" and "compound preparations of traditional Chinese medicines mainly used to treat syndromes", do not need to provide animal efficacy tests, but must conduct non-clinical safety tests. Conduct research to ensure drug safety.

5. The prescription contains toxic medicinal materials, raw materials for which no guidelines can be formulated, or non-clinical safety Traditional Chinese medicines that are found to have obvious toxic reactions in sexual experiments should first undergo Phase I clinical trials, but cannot directly undergo Phase II or Phase III clinical trials.

6. The research design should fully consider the effective and available clinical interventions of current modern medicine. approach and put the health interests of the subjects first.

7. Traditional Chinese medicine is no longer limited to traditional medicine. High-risk research projects should first be submitted to peer expert review to obtain evaluation opinions on the project. Ethical review committees review both the scientific and social value of research projects.

(2) Review of informed consent form.

1. The informed consent form should clearly state the different medical treatments currently available for the target disease of the study. Learn diagnostic methods and/or treatment status, and give subjects full freedom of choice.

2. The informed consent form should pay attention to the easy-to-understand terms and theories unique to traditional Chinese medicine. explanation of.

4. Terms and definitions

(1) Traditional Chinese Medicine: It is the collective name for the medicines of all ethnic groups in my country, including the medicines of the Han and ethnic minorities. It is a medical system that reflects the Chinese nation's understanding of life, health and disease, and has a long historical tradition and unique theories and technical methods. .

(2) Traditional medicine: It is the sum of all kinds of knowledge, skills and practices based on theories, beliefs and experiences unique to different cultures, whether explainable or not, used in maintaining health and preventing, diagnosing, improving or treating physical and mental diseases.

Appendix 6: Ethical Review of Stem Cell Clinical Research

1. General Stem

cell clinical research follows the "Stem Cell Clinical Research Management Measures (Trial)" and the "Stem Cell Preparation Quality Control and Preclinical Research Guiding Principles (Trial)" promulgated by the National Health and Family Planning Commission and the Food and Drug Administration.

The main purpose of stem cell clinical research is to verify the safety and effectiveness of preclinical research results, and to provide effective treatments for alleviating and preventing human suffering caused by diseases and injuries. Patients participate in clinical studies because they believe that these studies have been verified by good preclinical trials, and that the potential benefits of participating in the study are reasonable with the possible risks and burdens; doctors and the public can be confident that relevant national agencies are based on clinical research. Important medical decisions made based on the clinical evidence obtained are rigorous and fair.

In addition to following general ethical principles, stem cell clinical research also requires ethical requirements that are specifically applicable to stem cell clinical research, including clinical research using human embryos and germ cells. Some cell intervention-type research may have irreversible risks to subjects.

The current situation is the extreme vulnerability of critically ill patients who currently lack effective treatments and the urgency of their medical needs, as well as the high expectations of patients and the public for the development and accessibility of the medical field.

The goals of stem cell clinical research are to advance scientific knowledge in clinical medicine and to prioritize medical and public health needs. In clinical research, clinicians and researchers have the primary responsibility for avoiding putting subject patients at risk of harm and danger. Including experimental intervention trials, it is a process that must be completed before the clinical transformation of cell therapy and requires the participation of human subjects. The integrity and reliability of professional information obtained from clinical research should be ensured, and the professional information obtained will be used to guide patients. , doctors, and clinical researchers make relevant important decisions. Under rigorous, independent expert review of the safety and efficacy of stem cell therapies

It is against medical ethics to market it and apply it to a large number of patients before.

2. Key points of ethical review

The sponsor, clinical researchers, research conducting medical institutions, and regulatory agencies are all responsible for There is a responsibility to ensure that clinical trials are ethical. Like all clinical research, clinical trials of stem cell intervention must comply with internationally and domestically recognized ethical principles, scientific requirements and principles of subject protection.

(1) Institutional requirements 1. The

institution applying for ethical

review of stem cell clinical research must have obtained national

An institution registered for stem cell clinical research.

2. State-approved stem cell research registration institutions must establish specialized stem cell research

Research Academic Committee and Stem Cell Research Ethical Review Committee.

3. Ensure that the ethical review of stem cell clinical research has been approved by academic review before.

4. Stem cell clinical research also requires additional independent research evaluation in accordance with relevant regulations, including accepting hierarchical review or review required by the national authoritative management department or authorized

agency. (2) Research design

1. All clinical studies involving stem cell intervention must first be submitted to stem cell peer experts for academic review to make scientific judgments on the scientificity and effectiveness of the proposed stem cell clinical trial design. Both academic committees and ethical review committees should carefully examine the value of clinical research. If there is no relevant academic literature to refer to, ethical review must be based on professional and expert judgment.

2. For treatment models established by relatively new stem cell intervention, there may not be a pre-designed research plan, and it is impossible to propose a guided trial design. For this type of research, it is more appropriate to evaluate innovative medical methods. Promising innovative treatment strategies should be systematically evaluated as early as possible before large-scale implementation.

(3) Ethical review members

1. Participate in the review of the stem cell clinical research protocol by the Ethics Review Committee The membership must include experts with the ability to evaluate stem cell preclinical research.

2. Members participating in the review should include experts with the ability to evaluate clinical trial design, Includes experts in statistical analysis and clinical experts in special issues related to the disease.

3. The members participating in the review should include at least one researcher who has been engaged in stem cell-related basic, product development or clinical research for more than three years.

(4) Informed consent 1.

Researchers, clinicians and medical institutions should allow subjects to exercise effective informed consent if they have sufficient decision-making ability. Whether in a scientific or medical context, subjects should be provided with precise information about the risks of innovative stem cell therapies, as well as the current status of the development of innovative stem cell therapies.

2. If the subject lacks self-decision-making ability, a legal guardian should be used to consent, and the subject should be strictly protected from increasing risks beyond the minimum risk due to non-therapeutic procedures.

3. When conducting trials of interventional therapies on subjects who lack the ability to give informed consent, the risks arising during the study should be limited to the lowest risk, unless the associated therapeutic benefits far outweigh the risks. 4. With the consent of the legal guardian, if

there is a significant change in the risk-to-benefit ratio during cell intervention clinical research or alternative therapy research, the informed consent of the legal guardian must be obtained again. (5) Assessment of benefits and risks

1. Valid designs should be used to reduce risks and use the minimum number of subjects to appropriately answer scientific questions.

2. Based on current scientific understanding, recruitment is not allowed due to potential risks to the fetus.

It is legitimate and reasonable to recruit pregnant women as subjects to participate in stem cell clinical research.

(6) If clinical research involves the use of stem cells derived from embryos, the legal compliance of source and use should be strictly reviewed. (7) The use of stem cell interventions

beyond routine research should be evidence-based, subject to independent expert review and focused on the best interests of the patient. Promising innovative treatment strategies should be systematically evaluated as early as possible before large-scale implementation.

(8) Meeting review requirements

1. For ethical review of stem cell clinical research to be valid, the following conditions must be met:

(1) More than two-thirds of the legally present members must agree; (2) Researchers

with senior professional titles who are familiar with stem cell-related research among the members present must vote in favor. 2. The ethics review committee should

evaluate the researcher's statement of conflict of interest and ensure that

Ensure that conflicts of interest (financial and non-financial) that could bias the study design are minimized.

3. Stem cell clinical research data, including ethical review data, need to be kept for at least 30 years

Year.

Appendix 7 Clinical Application and Research Ethical Review of Human Organ Transplantation

1. General principles

(1) In order to protect the legitimate rights and interests of human organ donation and transplant recipients, advocate the humanitarian spirit of donating human organs to save lives, and standardize the ethical review of human organ donation and transplantation, in accordance with the "Regulations on Human Organ Transplantation" and "Ethics of Biomedical Research Involving Humans" Review Methods" "Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans"

"World Health Organization Guiding Principles for Transplantation of Human Cells, Tissues and Organs" and "Related

This supplement is formulated in accordance with the Ethical Review Measures for Human Biomedical

Research. (2) Institutions with clinical qualifications and scientific research capabilities for human organ donation and transplantation must set up ethical review committees in accordance with the requirements of the National Health Commission and ensure that ethical review work is carried out independently. Under the norms of national laws, regulations and relevant departmental rules and regulations, conduct independent review of the legality and ethics of human organ donation and transplantation, as well as the scientific and ethical nature of clinical research on human organ transplantation (drugs), and accept relevant management departments guidance and supervision. Ethical review committee procedures and guidelines for assessing the risks and benefits of organ transplantation, and whether there are judgments about the consequences of possible and uncertain events.

(3) This appendix applies to clinical applications of human organ transplantation and clinical research projects of human organ transplantation (drugs). The ethical review of the Human Organ Transplantation Ethics Review Committee should follow the principles of science, independence, fairness, impartiality and timeliness, and comply with relevant national regulations.

2. Key points of ethical review in clinical practice of organ transplantation (1)

Review committee

The human organ transplant ethics review committee shall be established at a medical institution or regional human organ transplant center (municipal, provincial, regional, national) that has registered human organ transplant diagnosis and treatment subjects.

countries) to establish and conduct independent ethics reviews.

The committee members should include experts in the fields of transplantation medicine, ethics, pathogenic microbiology, zoonotic epidemiology, law, sociology and other fields as well as non-institutional public figures, with experience in relevant subject training and review of organ transplantation technology applications. The number of medical personnel engaged in human organ transplantation shall not exceed one quarter of the total number of committee members, and the number of personnel who have no affiliation or interest relationship with medical institutions shall not be less than one quarter of the committee members.

When ethics committee meeting minutes, ethics review case materials and related documents are saved at least seven years.

(2) Conflict of interest

The committee members participating in the review should have no conflict of interest with this case of human organ transplantation, as follows: Anyone who falls into any of the following situations should avoid it immediately:

1. Doctors involved in determining death and performing organ harvesting or transplantation surgeries. 2. Have a spouse, blood relative within the fourth degree, or marriage relationship within the third degree with the donor or the person to be transplanted, or have had such a relationship. 3. There are other facts proving the suspicion of bias. 4. Those who have interests in applicants and participants of human organ clinical trial projects. 5. Other ethical decisions suggest situations that should be avoided.

(3) Confidentiality and privacy protection

Members and managers of the Human Organ Transplantation Ethics Review Committee must sign a confidentiality agreement regulations to protect patient and donor information. (4)

Scope of ethical review 1. The scope of review by the Human Organ Transplantation Ethics Review Committee includes the removal of human organs. Donor's organs with specific functions (e.g. heart, lungs, liver, kidneys,

The process of implanting all or part of the pancreas and small intestine into the recipient's body to treat or replace damaged organs.

2. Ethical review of cell, cornea, bone marrow and other human tissue transplantation does not apply to this guideline

South.

3. It is strictly prohibited to do anything to the human head (including the whole brain), the entire trunk below the head, and the gonads.

(testes, ovaries) and xenogeneic organs for clinical transplantation.

4. Follow the principle of “do not do anything unless you have to” and give priority to other more appropriate options.

Appropriate treatment

method. (5) The Human Organ Transplantation Ethical Review Committee has the responsibility to strive to ensure fairness and

justice in organ distribution. Including but not limited to:

1. Inquire about the registration system of the China Human Organ Donation Management Center, the voluntary organ donation

registration system for donors and recipients, the China Human Organ Distribution and Sharing System (COTRS), relevant OPO organizations

and the human organ transplantation management system of the health administration departments of various provinces, municipalities and

autonomous regions. .

2. When conditions permit, relatives/persons of organ donors can be invited to participate in the ethical review of organ transplantation.

3. To ensure that the procurement of

organs from the body must be judged by a specialist to be used after the death of the patient.

Organization of Obtainment (OPO) implementation.

4. After the brain death is determined and one of the following circumstances is met, organ donation is allowed

offer:

(1) The patient clearly expresses his or her willingness to donate organs before his or her death, and the patient’s spouse and direct

Relatives confirm their willingness to donate and agree to donate.

(2) The patient did not explicitly refuse organ donation during his lifetime.

All immediate family members agree to donate and sign a donation consent form, allowing organ procurement.

5. Recipients of living organ donation are limited to the living organ donor's spouse, direct blood relatives or collateral blood relatives within three generations, or there is evidence to prove that there is a family relationship with the living organ donor due to assistance (family relationship formed due to assistance) Should be limited to persons in an adoptive parent and adopted child, stepparent and stepchild relationship).

6. Living organ donors must be over 18 years old and have full capacity for civil conduct.

natural person. Persons under the age of 18 are not allowed to donate living organs, even if they voluntarily and with the written consent of their legal guardian. However, brain-dead persons under the age of 18 are allowed to donate organs with the written consent of their legal guardian and review and approval by the ethics committee.

(6) Before the hospital performs living organ donation transplantation, the following documents should be submitted to the Human Organ Transplantation Medical Ethics Committee for review and approval:

1. Donor's written consent and written proof from his close relatives.

2. Name, date of birth, gender, and relationship between the donor and the person to be transplanted

Information and certification.

3. Donor's psychological, social and medical evaluation information. 4.

Minors under the age of 18 must obtain written consent from their legal guardians to donate organs.

Consent (mortal organs only). 5. Evaluate

the indications and contraindications for transplantation of those waiting for transplantation. 6. Certification

materials from medical institutions and practicing physicians. 7.

Other supporting materials required by law.

(7) After a donor donates a living organ, the human organ ethics committee responsible for review must regularly follow up on the donor. For donors who need regular examination, the ethics review committee has the right to require the organ transplant hospital or physician to implement the organ transplantation procedure. Give assistance. (8) The Human Organ Transplantation Ethical Review

Committee must review organ harvesting, preservation,

Supervise and review the scientificity, fairness and ethics of transportation, distribution and use.

3. Ethical review of clinical research on organ transplantation and human organ transplantation (drugs) (1) When conducting ethical review of clinical research related to organ transplantation, the Human Organ Transplantation Ethical Review Committee requires that the applied organ transplantation clinical research project has been scientifically evaluated been fully reviewed and written review comments have been received.

(2) Members participating in the ethical review must include clinical experts in organ transplantation and not Participate directly in the study. Experts can be hired as research review consultants when necessary.

(3) Before ethical review of clinical research projects involving human organ transplantation involving relatively high risks, require the transplant team to provide a written scientific review report and an assessment report on the potential risks of the research project, and apply to the China Organ Donation and Transplantation Committee for assistance in the review or Provide advisory advice.

(4) The Human Organ Transplantation Ethics Review Committee shall conduct its review by voting. Decisions are made in a formal manner, and only decisions approved by more than 2/3 of all members can be effective.

(5) Human Organ Transplantation Ethical Review Committee's Research Practices on Organ Transplantation Supervise the implementation process and have the right to require explanations from applicants and relevant persons in charge.

(6) Researchers need to submit a conflict of interest declaration to the ethics review committee, and evaluated by an ethical review committee.

Appendix 8: Ethical review of relevant medical research during the outbreak period

1. General During an

epidemic outbreak, public health response and medical treatment capabilities should be ensured first to prevent research from affecting epidemic prevention and control. Prioritized research should be aimed at solving urgent problems that need to be solved in epidemic response, so as to quickly improve the ability of public health and medical systems to respond to epidemics. Necessary and urgent priority research mainly includes research on the epidemiology of the epidemic, prevention, diagnosis, treatment and rehabilitation of vaccines, diagnostic reagents, new drugs, new technologies and new intervention methods.

In order to ensure that relevant medical research is carried out in an orderly, standardized and efficient manner during the epidemic outbreak, we must This supplement is formulated to ensure the review timeliness and quality of the review by the Ethics Review Committee, improve the ability to respond to the epidemic, respect and protect the legitimate rights and interests of subjects, and safeguard human dignity, life and health. This appendix applies to medical research projects

related to the epidemic during the outbreak.

This document serves as an appendix to the "Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving Humans" and is a supplement to the Guidelines.

2. Organization and management

(1) Ethical review committees at all levels should pre-formulate relevant systems and procedures for ethical review of epidemic-related research during the outbreak. According to the "Law of the People's Republic of China on the Prevention and Control of Infectious Diseases", the "Regulations on Emergency Response to Public Health Emergencies", the "National Emergency Plan for Public Health Emergencies" and other provisions, when an infectious disease breaks out or becomes popular, the health administrative departments at all levels shall issue emergency announcements to the public. After public health event warning information is issued, relevant systems and procedures should take effect immediately. (2) The ethics review committee should establish a remote review and discussion platform in advance to

It will facilitate committee members to carry out review work; establish a communication mechanism with researchers to facilitate discussions on relevant research.

(3) The ethics review committee should provide relevant training to the committee members who are expected to undertake ethical review tasks, so that they can conduct efficient and high-quality review work during the epidemic.

(4) The chairman of the ethics review committee shall make a decision based on the relevant professional fields of the research and Identify potential risks and review members, and invite independent consultants to participate in the review if necessary.

(5) The review members should provide a conflict of interest statement before the review to ensure that the review independence and impartiality.

(6) The ethics review committee should pre-determine specialized personnel to be responsible for the outbreak Liaise during the period and keep records of all communications and archive them.

3. Review methods and requirements

(1) The urgency of conducting epidemic-related research during an outbreak poses a huge challenge to the review work of the ethics review committee. The ethics review committee should insist on conducting independent and impartial reviews of research projects based on the highest scientific and ethical standards to ensure the quality and timeliness of ethical reviews. (2) In order to shorten the review time limit as much as possible, during the outbreak, the ethics

review committee should use online meetings and review procedures as much as possible, and members should devote as much time and energy to the review of epidemic-related research as possible.

(3) The ethics review committee should determine in advance the minimum quorum for meeting review during the outbreak. The quorum may include independent advisors, who shall provide a declaration of conflicts of interest prior to the review. (4) The ethics review committee should formulate the review procedures that need

to be submitted for epidemic-related research.

List of information. The information provided by the researcher should be as simple as possible and should at least include:

1. A description of the relevance of the research to the epidemic;

2. A description of the preliminary research data on the epidemic in this study; 3. A description of

the qualifications of the institution and research team members responsible for and conducting the study,

Including whether you have participated in epidemic-related research work and whether you are competent in relevant research;

4. Research plan; 5. Informed

consent; 6. Measures to protect

the privacy and confidentiality of subjects; 7. Damage compensation plan for subjects;

8. Declaration of conflicts of interest; 9. Multi-center clinical

research should coordinate all

participants The research institute also provides consultation on a

Ethical review opinions (if applicable).

(5) In order to improve the timeliness of the review, the ethics review committee may first accept the electronic version of the application

Materials (paper materials are allowed to be submitted later).

(6) The project leader should communicate with the ethics review committee as soon as possible to explain the research intention,

research content and plan, so that the ethics review committee will know the willingness to submit the research application and prepare for the review.

(7) The ethics review committee should try its

best to shorten the review time while ensuring the quality of the review: review materials should be sent to the committee members for

pre-review within the specified time after formal submission, and the ethics review committee should complete the review within the specified time

after the committee members' pre-review. Review opinions and suggestions should be communicated to the project leader within the specified time

after the review. If the project leader needs to communicate with the ethics review committee regarding review opinions and suggestions, electronic

communication should be used whenever possible. (8) The ethics review committee should strengthen the follow-up review and supervision of

research projects

Management work, including review of amendments, review of serious adverse events, etc.

4. Review content and requirements

(1) Even in emergency situations, without prior review by the ethics review committee and approval, clinical research using human subjects is not allowed. When emergency medical treatment involves the use of an investigational drug, device, or biological agent, the patient should not be considered a subject of the emergency clinical investigation. This type of emergency treatment is medical treatment rather than research, and must be implemented in accordance with relevant national laws, regulations, departmental rules and regulations. Any data related to this treatment cannot be included in any prospective study report. (2) Epidemic-related research should be based on the highest standards of science and ethics, especially research projects carried out in emergencies that involve first-time application to humans and have extremely uncertain risks, to protect the safety and rights of subjects and ensure the public Trust in scientific research and its scientific results is particularly important.

(3) The ethics review committee should review the institution's ability to undertake and conduct research. For urgent, high-risk or uncertain research projects, it should be ensured that they are conducted in institutions that are competent and adhere to the highest scientific, clinical, and ethical standards. These institutions should have experience in designing, reviewing, and conducting similar studies, have available facilities and equipment, be able to provide safe and high-quality treatment and care to subjects, and be able to provide intensive care and conduct necessary follow-up when necessary. , be liable for damages related to research. (4) Although it is urgent to carry out relevant research projects during the outbreak, the ethics review committee must still judge the scientific nature of the research based on the highest scientific standards, including: the basis for project establishment; the scientific rationality of the research design, such as sample size estimation,

The rationality of the control group selection and randomization grouping, the objectivity and rationality of the efficacy index evaluation criteria; whether the research results can provide clear evidence of effectiveness and safety.

Research with higher and/or uncertain risks should be subject to more rigorous scientific evaluation: 1. The purpose of the research is to

obtain research results so that the epidemic situation of the disease can be obtained as soon as possible Learn knowledge, obtain prevention, detection, diagnosis and treatment intervention measures, and quickly use them to respond to the epidemic to achieve greater public health and medical benefits;

2. Whether it is impossible to obtain valid research results using a lower-risk research design;

3. Does the research design expose subjects to avoidable risks and harm? Minimize possible harm to subjects and ensure public trust in research;

4. The research results have broader generalizability, can be widely and effectively used in public health and medical response interventions, and can protect and diagnose a wider and/or higher-risk population; provide reliable and effective information for future research. data evidence.

(5) The ethics review committee should review the rationality of the subject selection criteria. 1. The safety of

subjects and the acceptability of potential risks are the priority criteria; 2. Ensuring that the potential risks that subjects

may suffer are minimized, which is key and necessary for the research project to be ethically acceptable. conditions; 3. Avoid taking inappropriate advantage of vulnerable groups,

including (but not limited to) social status and economic Vulnerable groups at high risk of contracting the disease who are in a disadvantaged economic situation; vulnerable groups who may be subject to coercion (including disguised coercion); vulnerable groups who bear greater psychological and/or physical risks by participating in research;

4. Subject selection Standards should be updated promptly based on the latest research results and new evidence, and people with lower risk should be selected as subjects whenever possible. Subjects excluded as much as possible

Including (but not limited to): people with higher risks; people who are at major health risks and harms due to participation in research; 5. It should be avoided as much as possible to avoid combining

public health and epidemic prevention with medical personnel who are directly involved in responding to the epidemic.

Medical and medical personnel will be included as subjects to protect the necessary resources and capabilities to respond to the epidemic.

(6) The ethics review committee should pay special attention to assessing the possible risks and benefits of epidemic-related research.

1. The possible risks and benefits of the research

should be compared with other feasible related research designs;

2. The possible benefits of research should outweigh the risks;

3. The benefits should be maximized as much as possible without increasing the risks to the subjects;

4. Risks should be minimized as much as possible without compromising the scientific value of the research;

5. Risk minimization strategies should be included in the research design; 6. The assessment of

research risks and benefits and risk minimization strategies should at least consider: subjects, society, and contacts of subjects, and risk and benefits should be ascertained as much as possible. Conduct quantitative assessments. (7) The ethical review committee should pay special attention to the

informed consent and informed consent process of the research. In view of the special circumstances during the outbreak, it is expected that subjects will be obviously vulnerable, their autonomy will be challenged, and they will be easily exploited, especially research projects involving high risks and risk uncertainty. Ensure that subjects should be fully informed, Under the premise of fully understanding the possible risks of the research, you voluntarily choose to participate in the research.

(8) The ethics review committee should pay special attention to the privacy protection measures for subjects. 1. It should ensure

that research projects have adequate measures to protect the privacy of subjects and maintain the confidentiality of personal information of subjects; 2. When the personal health

information of subjects needs to be used for major public interests, it must

With valid authorization;

3. During the outbreak, subjects participating in the study may be transferred to different diagnosis and treatment settings. Special attention should be paid to protecting the privacy of subjects during the referral process, and confidentiality measures should be formulated and strictly implemented in terms of information collection, storage, transmission and information use.

(9) The ethical review committee should pay special attention to balancing possible conflicts of interest in research, including (but not limited to) the conflict between the researcher's personal academic benefits and the mission of the medical scientist; the conflict between the use of limited resources (for example, competing subjects, Conflicts between medical treatment resources and scientific research resources, medical treatment and public health response resources).

5. Unity, collaboration, supervision and management of research and review

(1) During the outbreak, research project decision-making agencies, regulatory agencies, researchers, and funders should collaborate closely, establish a research collaboration mechanism, encourage multi-center research, and ensure effective subject samples. Research designs should be as standardized as possible to avoid unnecessary duplication of studies. (2) In view of the limited medical and research resources during the outbreak and the

importance of effective use of resources, clinical research should be carried out in an orderly manner to prevent research from affecting patient treatment and overall epidemic prevention and control. Researchers need to be self-disciplined, rigorous and scientific in designing clinical studies to ensure the authenticity and objectivity of research results and avoid conflicts of interest.

(3) All emergency research related to the epidemic should also be carried out in the Medical Research Center of the National Health Commission. Register in the research registration and filing information system.

(4) Establish a rapid solidarity and sharing mechanism for research results, especially information related to epidemiological research results, the safety and effectiveness of response intervention measures, and possible harm to subjects.

(5) Establish an ethics review coordination and collaboration mechanism to accept national and provincial ethics

Oversight and management of review committees. During the epidemic, the leading institution of a multi-center study conducts epidemic-related research at the research site institution. The ethics review committee of the leading institution and the research site institution will work together to conduct ethical review and be responsible for tracking and supervising the implementation of the research project.

(6) Establish a supervision mechanism for the release of research results and results. Relevant research results should be released scientifically, objectively and accurately in accordance with laws and regulations. Research results may not be released to the media without peer review. Research institutions bear the main responsibility for the release of scientific research information.

(7) Strictly abide by relevant national requirements on human genetic resources and biosafety. Anything involving the export of human genetic resources or that must be approved by relevant departments in accordance with national regulations must be declared to and approved by the relevant departments before project implementation. Research involving the research, detection, and diagnosis of pathogenic microorganisms for infectious diseases must be conducted in accordance with relevant national and local regulations. Strengthen researchers' review of personal protection, sample management, and waste disposal to ensure biosafety.