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Interpretation of the document "Measures for Ethical Review of Life Sciences and Medical Research Involving Humans"

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1. Why was the Measures issued?

Adhering to the concept of "people first, life first", in order to protect human life and health, maintain human dignity, respect and protect the legitimate rights and interests of research participants, promote the healthy development of life sciences and medical research, and regulate life sciences and medicine involving human beings Research ethics review work is carried out in accordance with the Civil Code of the People's Republic of China, the Basic Medical Hygiene and Health Promotion Law of the People's Republic of China, the Science and Technology Progress Law of the People's Republic of China, the Biosafety Law of the People's Republic of China, and the Management of Human Genetic Resources of the People's Republic of China. Regulations, etc., and formulated the Measures.

2. What specific research does life science and medical research involving humans include?

The term "life science and medical research involving humans" as mentioned in the "Measures" refers to the following research activities using human subjects or using biological samples and information data of humans (collectively referred to as research participants):

1) Activities that use physics, chemistry, biology, traditional Chinese medicine and other methods to study human reproduction, growth, development, aging, etc.;

2) Activities that use methods such as physics, chemistry, biology, traditional Chinese medicine, and psychology to study human physiology, psychological behavior, pathological phenomena, disease etiology and pathogenesis, as well as disease prevention, diagnosis, treatment and rehabilitation, etc. ;

3) Activities that use new technologies or new products to conduct experimental research on humans;

4) Use epidemiological, sociological, psychological and other methods to collect, record, use, report or store biological samples, information data (including health records, behaviors, etc.) related to human life sciences and medical issues and other scientific research data activity.

3. Which institutions should establish ethical review committees, and what are the main considerations?

The "Measures" stipulate that medical institutions at level 2 or above that carry out research involving human life sciences and medicine, health institutions at or above the districted municipal level (including disease prevention and control institutions, maternal and child health care, blood collection and supply institutions, etc.), universities, and scientific research institutes Institutions should establish an ethics review committee.

The main consideration is that the institution's establishment of an ethics review committee is not only a recognition of the institution's research management capabilities, but also a policy obligation that the institution should fulfill. In order to effectively protect the rights and interests of research participants, it fully reflects the professional requirements for ethical review of life sciences and medical research involving humans. , made the above provisions.

4. Do other institutions require ethical review when conducting life science and medical research involving humans? How to carry out ethical review?

Ethical review must be conducted as required when conducting life science and medical research involving humans. In order to achieve comprehensive coverage of the above-mentioned research ethics review, the "Measures" stipulates that if an institution conducts life science and medical research involving humans without establishing an ethics review committee or the ethics review committee is unable to meet the review needs, the institution may entrust a competent institutional ethics review The committee or regional ethics review committee conducts ethical review and requires the entrusted ethics review committee to conduct follow-up review of the reviewed research.

In view of the fact that medical and health institutions mainly carry out clinical research and have high requirements for risk control, the "Measures" also require that medical and health institutions should entrust the ethics review committee or regional ethics review committee of a medical and health institution not lower than its level to conduct ethical review Require.

5. How do companies conduct ethical review when conducting life science and medical research involving humans?

The "Measures" stipulate that if enterprises and institutions cooperate in conducting research, the institution shall fully understand the overall situation of the research, pass ethical review, and conduct follow-up review. If an enterprise conducts research independently, it can entrust an institutional ethics review committee or a regional ethics review committee to implement extended supervision through follow-up review.

6. Does the Measures have any special provisions for specific groups of people?

Specific groups of people are the focus of ethical review. In order to strengthen the protection of the rights and interests of specific research participants, the "Measures" clearly put forward the requirements for "special protection" in the basic requirements for ethical review, stipulating that specific research involving children, pregnant women, the elderly, people with intellectual disabilities, people with mental disorders, etc. Group research participants should be given special protection, and special attention should be paid to those involving fertilized eggs, embryos, fetuses, or those that may be affected by assisted reproductive technology.

At the same time, the "Measures" stipulate: respect and protect the right to know and the right to make independent decisions of research participants or guardians of research participants, and do not allow the use of deception, inducement, coercion and other means to obtain the consent of research participants or guardians of research participants to participate. Research allows research participants or research participants' guardians to withdraw from the research unconditionally at any stage. The special chapter on informed consent further stipulates that if research participants are persons without or with limited capacity for civil conduct, they must obtain written informed consent from their guardians. While obtaining guardian consent, researchers should also inform research participants of

relevant information within a range that can be understood and obtain their consent.

7. How are the "Measures" and the "Measures for Ethical Review of Biomedical Research Involving Humans" applied?

In order to strengthen the legalization of the ethical review of biomedical research involving humans in medical and health institutions and clarify legal responsibilities, the former National Health and Family Planning Commission issued the normative document "Measures for the Ethical Review of Biomedical Research Involving Humans" issued by the former Ministry of Health in 2007 ((Trial)" was revised, and the "Ethical Review Measures for Biomedical Research Involving Humans" (former Health and Family Planning Commission Order No. 11) was issued in the form of departmental regulations in 2016. The scope of application of Order No. 11 is all types of medical and health institutions at all levels that carry out biomedical research involving humans, and details the administrative penalties for violation of regulations.

As my country's investment in scientific and technological innovation continues to increase and biotechnology develops, universities and scientific research institutes are increasingly involved in life sciences and medical research involving humans. The Party Central Committee and the State Council attach great importance to safeguarding the rights and interests of research participants and actively promote the establishment of a unified ethical review system. To this end, the National Health Commission, together with the Ministry of Education, the Ministry of Science and Technology, the Bureau of Traditional Chinese Medicine and other relevant departments, have formulated the "Measures" to provide a unified ethical review system for medical and health institutions, universities, scientific research institutes, etc. to conduct relevant research, and The departmental division of labor for supervision and inspection has been clarified.

The "Measures" are generally consistent with the main institutional framework, ethical review methods, informed consent, etc. of Order No. 11, and some provisions have been refined and combined with the requirements of newly introduced national laws and regulations and the actual conditions of universities and scientific research institutes. Complete. Within a certain period of time, the specific ethical review practices of institutions can be guided by the "Measures"; for violations of ethical review of medical and health institutions, health administrative departments at all levels can handle them based on Order

No. 11. Our committee will make an in-depth summary of the parallel situation between the "Measures" and Order 11, and initiate the revision of Order 11 in a timely manner to further improve supervision. Violations of regulations by other agencies will be handled by their superior authorities in accordance with administrative affiliations.

8. Comparing the "Measures for Ethical Review of Biomedical Research Involving Humans", what adjustments have been made to the "Measures for Ethical Review of Life Sciences and Medical Research Involving Humans"?

The "Measures for the Ethical Review of Life Sciences and Medical Research Involving Humans" adhere to the basic principles and institutional framework of the "Measures for the Ethical Review of Biomedical Research Involving Humans", which mainly include: First, upholding the responsibility of the institution's main body, requiring institutions to establish an ethics review committee to review Conduct ethical review of life science and medical research involving humans; second, adhere to the two pillar systems of informed consent and ethical review; third, adhere to internationally recognized ethical principles and adhere to basic ethical requirements. At the same time, it has been optimized and improved based on the actual situation, and unified guidelines have been proposed for different research subjects to carry out life science and medical research involving humans.

(1) Expand the scope of application of ethics review and clarify departmental supervision responsibilities according to administrative affiliations. "Biomedical research involving humans" will be expanded to "life science and medical research involving humans", and life science research involving humans will be included in the scope of management. The management objects will be expanded to include medical and health institutions, colleges and universities, scientific research institutes, etc., and the supervisory responsibilities of ethical review will be clarified according to the administrative affiliation.

(2) Establish an entrusted review mechanism to allow competent ethical review committees to be entrusted to conduct ethical reviews. The first is to establish a commissioned review mechanism to achieve comprehensive coverage of ethical review. It is clarified that institutions that do not have an ethics review committee can entrust in writing a regional ethics review committee or a capable institutional ethics review committee to conduct ethics review; second, it proposes management requirements for regional ethics review committees, which is an important exploration to further improve the efficiency of ethics

review. Third, when enterprises conduct research, they can implement ethical review supervision through entrusting ethical review and clarify supervision and management responsibilities.

(3) Optimize ethical review standards and refine informed consent procedures. The first is to refine the provisions on the informed consent process for research participants who are incapacitated or have limited behavioral capacity. The second is to expand "subjects" to "research participants" based on the progress of biomedical research and bioethics, strengthen respect for people, and expand the scope of protection. The third is to balance norms and innovation and establish an "exemption from ethical review" institutional arrangement. Fourth, the time limit for ethical review has been specified in detail to further improve efficiency.

9. How to balance the relationship between reducing the burden on scientific researchers and ethical review? Which research is exempt from ethical review?

Considering that most basic research activities do not directly involve human trials, and some studies do not directly involve clinical diagnosis and treatment information of research participants, drawing on internationally accepted practices, in order to improve review efficiency and reduce unnecessary burden on scientific researchers, the "Measures" stipulates "On the premise that the use of human information data or biological samples does not cause harm to the human body, and does not involve sensitive personal information or commercial interests," life sciences and medical research involving humans can be exempted from ethical review in some cases. mainly include:

1) Conduct research using legally obtained public data, or data generated through observation without interfering with public behavior;

2) Conduct research using anonymized information data;

3) Conduct research using existing human biological samples. The sources of biological samples used comply with relevant laws and ethical principles. The relevant content and purpose of the research are within the scope of standardized informed consent, and do not involve the use of human germ cells, embryos and Reproductive cloning, chimerism, heritable genetic manipulation and other activities;

4) Conduct research using human cell lines or cell lines derived from biobanks. The relevant content and purpose of the research are within the scope of the provider's authorization, and do not involve

human embryonic and reproductive cloning, chimerism, heritable genetic manipulation, etc. active.

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