

Research on Ethical Review System of Human Research in the Medical Field in China

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Keywords: Medical research; Ethical review; Institutional research

Abstract: In recent years, the development of ethical review in the field of medical research in China has achieved specific results, but it must be recognized that there are still some deficiencies and contradictions in the ethical review system of human research. Under this situation, this article emphasizes the importance of an ethical review of human body research from the characteristics and primary connotation by expounding the theoretical basis of the review system of human body research ethics. Then, this paper profoundly explores the main problems and reasons for ethical review in human research in China and puts forward targeted improvement suggestions.

1. Introduction

China's ethics review system has made some progress in recent years. However, the construction of China's ethics review system has not yet received widespread attention, and medical research institutions' internal ethics review committees have not yet established a mature system. The ethics review system's primary purpose is to supervise medical research involving human experiments in the ethical field, resolve conflicts of interest in human research, and minimize the probability of researchers making mistakes. Based on this background, this paper analyzes the ethical review system's reasons, main characteristics, and development process. During the investigation, we found that China's ethical review system is insufficient at the theoretical construction level. It is difficult to guarantee the independence of institutions, and there is no relationship between negation and negation between the specific actions of ethics review committees at different levels. Regarding the existing problems, this paper puts forward relevant suggestions to ensure that the ethical review system respects the researchers' pursuit of science and, at the same time, uses an objective perspective to protect the rights of the experimental groups, making the procedures fair and just, and improving efficiency.

2. Theoretical Basis of Research Ethics Review System

2.1 Study for Human Body

In lay terms, human body research in the medical field is also called human experimentation, which specifically refers to a series of medical activities that take the human group as a specific research object. All behaviors in the medical activity should follow the pre-designed plan and use specific methods to observe and study the experimental subjects. Primary human body research includes multiple medical disciplines such as surgery, imaging, and pharmacy, and it even involves psychology.

It must be noted that, unlike clinical treatment practice, human medical research is not aimed at a specific individual but at verifying or acquiring new knowledge in experiments. In addition, unlike scientific research in other disciplines, the specific experimental objects of human body research are human beings, including healthy natural persons and patients. It is an essential factor prone to ethical contradictions in human research. However, from another point of view, these subjects also participate in medical and scientific research. According to the statistical data in recent years, in the development of many new drugs in China, the number of people involved in the research is vast.

Some large-scale research even involves tens of thousands of people. For such a vast group, protecting its various rights and interests is an important issue that must be paid attention to.

2.2 Ethical Review System

In many kinds of research for the human body, regardless of the period, due to the conflict of interests of different groups, it is difficult to avoid the event that the interests or rights of the subjects are challenged. Taking double-blind trials as an example, the issue of whether researchers should obtain the consent of subjects in advance is one of the hot spots in ethics research. In international human research projects, it is often difficult to ensure uniform ethical standards in experiments in developing and developed countries, and subjects in relatively underdeveloped regions will be harmed in human experiments [1]. At the same time, their self-protection awareness continues to increase. In this case, the ethical review system came into being and has been paid more and more attention to and studied by people. Its primary purpose is to supervise the ethical field of medical research involving human experiments, resolve various conflicts of interest in human research, and minimize the chance of researchers making mistakes.

From the analysis of the reasons, the ethical review system comes from a thorough reflection on human nature. It is necessary to admit that selfishness, desires, and even extreme factors exist in human nature. Sometimes these elements can blind the eyes of various groups, including medical researchers, expose the flaws in human nature, and affect the fairness of research. In order to make a good plan, people use rational thinking in the early stage of human body research to analyze the possible adverse consequences of each link in the research process and realize that even good original intentions may bring harmful consequences. Out of a responsible attitude, the ethical review system uses a relatively objective perspective to protect the rights of the experimental groups while respecting the pursuit of scientific ideals by researchers [2].

2.3 The Development of the Ethical Review System of Human Research in China

The establishment and development of the ethics review system are inseparable from the participation of the ethics review committee. As early as the 1980s in China, academic circles began to discuss the possibility of establishing an ethics committee. In 1998, China tentatively promulgated the "Measures for the Ethical Review of Biomedical Research Involving the Human Body", which can be regarded as the germination of the ethical review of human body research in the medical field in China, and a breakthrough was made in 2007 to improve and modify it. In the following year, to standardize drug use in clinical trials, China promulgated the "Pharmaceutical Clinical Trial Management Regulations" and continued to improve and revise them. In 2000, China formally established an official ethics review body, the Medical Ethics Expert Committee of the Ministry of Health. The following year, China clarified that institutions engaged in artificial assisted reproductive technology research must set up internal ethics committees [3]. In 2016, the "Measures for Ethical Review of Biomedical Research Involving Humans" was officially implemented, which marked the improvement of China's ethical review system, and the level of ethical review in the field of human medical research in China has also been improved by leaps and bounds.

However, the study found that many research projects did not apply for ethics review. Even for papers published in some high-impact medical journals, the medical experiments involved often include the issue that the subjects did not obtain informed consent and have not undergone ethical review [4]. Hospitals at or above the city level have a higher proportion of conscientiously implementing ethical review regulations in medical research. This shows that the establishment of China's ethics review system has not yet received widespread attention, and many medical research institutions' internal ethics review committees have not yet established a mature system.

3. The Importance of Ethical Review on Human Research in China

3.1 Main Characteristics of Ethical Review in China

The establishment and improvement of China's ethical review system have been committed to

learning from the independent structure of the West. However, it must be admitted that most of China's current ethical review committees cannot be independent. The ethics review committee is not a single individual but is set up under the banner of hospitals, schools, and even some research institutions. The reason is that the staff of the ethics review committee also come from these units. At the same time, the subjects participating in human experiments are often not independent, and the recruitment notices of subjects in medical research projects are often disseminated through scientific research and workers in various institutions. That is, the subjects come from friends and colleagues of these people or even relatives. The correlation between the subjects and the researchers and related personnel brings certain difficulties to the subjects in maintaining independence in the experiment. This means that the most crucial feature of ethical review in China is non-independence [5].

More importantly, the social status of doctors in China has always been at a relatively high level. Especially after the Song Dynasty, under the influence of Confucianism, people even regarded medicine as "benevolence". Doctors can not only relieve people's pain, but their various activities are even practicing the important ideas of Confucianism rather than getting money. For a long time, doctors and medical researchers have been regarded as worthy of respect, and they are often unlikely to be flawed or corrupted. For such a great group, the design and implementation of an ethical review system is a question of their morality, and it is easy to affect the enthusiasm of medical practitioners.

3.2 The Connotation of Ethical Review in China

First of all, from the perspective of cognition, the study of ethical review in China has the connotation of kindness. The crucial point in ethical review is to examine and analyze the main motives of human research in the medical field scientifically, calmly, and objectively and to judge what researchers should and should not do from all aspects. These rules and regulations set up the morality and character that medical practitioners should uphold [6]. These censorships are not just for acquiring the broad medical knowledge of each science but for practicing the essence of goodness, which is to safeguard the subjects' rights while doing scientific research. This maintenance can minimize the risk of scientific research and ensure that medical practitioners conduct research within the framework stipulated by the system, which is the institutional protection for the development of human body research.

Second, for practice, ethical review in medical research should be positive. That is, researchers should have a high sense of social responsibility. As an active individuals, in addition to having rich medical research methods and knowledge, medical researchers should also fully and consciously fulfill professional ethics and actively restrain themselves by constantly examining their behavior. While practicing the principles of temperance and justice, researchers learn to control their emotions and desires, resist the temptation of interests, and make their behaviors conform to institutional and moral norms in all aspects of participating in human body research.

4. Reflection on the Ethical Review System of Research for the Human Body in China

4.1 Major Issues in Ethical Review in Human Research in China

First, China's ethical review system is insufficient in terms of theoretical construction. On the one hand, ethical review is a concept imported from the West, and there is still room for Chinese people further to deepen their understanding of the ethical review system. Specifically, whether it is easy to understand from the perspective of epistemology or the source of the ethical review system, China still has subjective misunderstandings about the theory and practice of ethical review. Some concepts have not been improved in combination with China's actual national conditions and are directly cited, which makes China's ethical review system insufficient. On the other hand, there are inconsistencies in the various laws and regulations related to ethical review promulgated by China, which leads to conflicts in the effectiveness of laws. For some clinical research projects, approval is sometimes obtained through only a legal review. Even if there are violations of laws and regulations

in some human body research projects, it is often difficult to become a legal case. Under most conditions, administrative methods can only supervise and deal with it, so the binding force is insufficient. In this case, China's ethics review system is often reduced to a formality.

Second, the independence of China's ethics review agencies is difficult to guarantee. Ethics review is aimed at respected medical practitioners and scientific researchers. Scrutiny of these groups is a challenge to their status. More importantly, however, China has clearly defined the responsibilities and authorities of the ethical review body. Due to the non-independence of the ethical review body, the possibility that the internal ethical review body of the organization will not approve the study application for the study projects applied by hospitals, colleges, and universities is relatively low. In this case, even if the review committees of some institutions can maintain independence and objectivity and exercise strict constraints and supervision on human research projects, people will be questioned.

Finally, there is no negative relationship between the specific actions of our different levels of ethical review committees. Simply put, the higher-level review committee does not have the right to deny the research review of the lower-level committee. In China, even the National Ethics Review Committee cannot overturn the decision and ultimately restore the original state of the research when they learn that there is a problem with the consent application decision of the lower-level institution. They can only use the method of post-supervision to investigate and deal with it. This means that many ethical issues in human research, especially major ones, are difficult to supervise by the authority of review agencies at all levels.

4.2 Cause Analysis

First, there are problems in China's medical and medical research institutions. China's medical institutions involved in human research will not break through the restrictions of administrative divisions in a short period. These medical systems have geographical restrictions at different levels, such as the country, province, city, district, and county. Correspondingly, the ethical review committees within these medical institutions cannot break through geographical restrictions, and some ethical review committees may even become affiliated with these medical organizations. If the ethics review committee wants to obtain an independent status, it must set up an independent legal person with independent funding channels and personnel organization. With this framework, China's ethics review system can strictly fulfill its responsibilities and continuously improve the supervision mechanism in practice.

Second, Chinese society does not have a good understanding of human research. All social groups need to further increase their attention to human research in the clinical field. Against this background, even if there are ethical issues in some human research projects, it is not easy to obtain social responses quickly. We must admit that the lack of attention has restricted the acquisition of legislative conditions in the field of ethics review.

At the same time, the lack of awareness of human body research also prevents people from establishing subconscious rights protection reflections when facing human body research subjects and naturally lacks systematic rights protection rules. So far, China has only clearly stipulated the rights and interests that patients should enjoy at the legal level, such as the "Law of Practicing Physicians", and the protection of the rights and interests of human research subjects is still blank.

4.3 Suggestions for the Improvement of the Ethical Review System in Human Research in China

In order to further prevent ethical problems in human research projects in medical research, the government should set up the highest-level ethics review agency. When serious ethical issues arise during experiments, such as human gene editing and other events, the highest-level ethics review committee should break through the limitations of the internal review committee of medical institutions and conduct reviews following strict procedures. Furthermore, the ethical issues involved in the type and level of human research projects should be supervised and managed by China's highest ethical review agency. They must be divided and even regulated at the legislative level. It is an important way to ensure the authority of China's ethical review system.

In order to improve the degree of legalization of ethical review in human body research in the medical field, we should also try our best to promote the independence of ethical review agencies at other levels. To ensure the independence of personnel, funds, and other aspects, the review agency can better handle the interesting relationship among different groups such as fund sponsors, project applicants, and subjects to ensure the fairness and efficiency of the ethical review of each project.

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