

Legal Progress in the Protection of the Rights and Interests of Human Subjects in Biomedical Research in China

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Abstract. The rapid development of biomedical technology in China requires much research and a large number of human subjects have emerged in response. Chinese government has been sparing no efforts in protecting the rights of human subjects by the law and has made further achievements in 2016. This article finds that the laws are being improved, the ethical principles have been growing clearer, the validity of informed consent has been better guaranteed and the gap that the law fails to fill has been compensated for in legislation in China. Though legislative technique and legislation in this field need improvement, the legal guarantee of the rights of subjects is promising.

Introduction

For the past decade, China has made remarkable achievements in biomedical research. But the subjects in biomedical studies have been disadvantaged because of low economic and social status, lack of full access to specialized knowledge and information and thus exposed their health to the great risks. Take the drug clinical trials as an example, the subjects in china has reached around 500,000. Their rights should be protected by the laws. Chinese government has been trying to improve the protection of their rights and interests. Undoubtedly, ethical review and informed consent as the two pillar stones for protecting rights of subjects have been improved. Rules for the Ethical Review of Biomedical Research Involving Human Subjects (referred to as Rules below) came into effect in 1 December 2016. It revised its articles to improve itself in this regard, representing the latest legal progress in China. This article will elaborate on the trend of legal protection of biomedical research combined with the revision made in the Rules.

The Legal Protection of the Rights and Interests of Subjects Has Been Improved and Growing Increasingly International

China started to protect the rights and interests of subject in 1990s. The State of China Food and Drug Administration (referred to as SCFDA) and the Ministry of Health announced Good Clinical Practice (referred to as GCP), which offers standardised drug clinical practice and requires that the rights and interests of subjects be protected. In 2007, the Ministry of Health announced the Interim Rules for the Ethical Review of Biomedical Research Involving Human Subjects. It offers standardised practice of studying human physiology or pathology, or methods of the diagnosis, treatment or prevention of disease with human subjects in terms of modern physics, chemistry and biology.

These laws attach importance to and learn from the international experience. For example, the laws refer to International Guidelines for Ethical Review of Biomedical Research Involving Human Subjects and Declaration of Helsinki (DoH) by the World Medical Association for information concerning the research activities defined for ethical review. The Rules has also included activities such as collecting, recording, using, reporting or storing information of human subjects, medical records and practice in terms of epidemiology, sociology, psychology. For another instance, GCP established the principles of human subject protection as defined in the Declaration of Helsinki, and has attached the DoH as an annex and made it legal as part of the national law. The principles for human subject protection established in treaties including Declaration of Helsinki, Universal Declaration on the Human Genome and Human Rights , and International Ethical Guidelines for Biomedical Research Involving Human subjects and that basic rights of human subjects should be protected are written into the laws in China, which ensures China to keep up with the international move in protecting rights and interests of human subjects.

The Rules has made revision in the set-up of ethical review committee, principles for ethical review, liability targeting the problems resulting from the Interim Rules coming into effect in 2007. At the same time, the Rules have been upgraded as the regulations from the Interim Rules as the general rules, which shows the importance that Chinese government attach to the protection. It is promising that the legal status of protection of rights and interests of human subjects will be further improved.

Ethical Principles That Should Be Conformed to in Biomedical Research Has Grown Clearer

Ethical principles of human subject protection for biomedical research have been embedded in the relevant laws in China. For instance, the Article 4 in GCP reads: all the research involving human subjects should conform to the principles in Declaration of Helsinki, to be just, to safeguard human dignity, and maximize the benefits and minimizes the harm that the human subjects are subject to. The Interim Rules and Norms on Quality Management for the Clinical Trials of Medial Devices (referred to as Norms below) has also established the principles for ethical review in biomedical research involving human subjects. For example, Article 14 in the Interim Rules reads that the principles for ethical review of biomedical research involving human subjects should be:

Respecting and ensuring the rights of subjects to autonomously make their own decision to agree or disagree to participate in research, strictly following the informed consent procedures, prohibiting undue means, such as deception, inducement, threat for making people agree to participate in, and allowing subjects to withdraw from the research period.

The safety, health, rights and interests of subjects shall be put on the priority over scientific and social interests. The efforts shall be made to make subjects to get maximum benefits and to minimize the harm.

But the Interim Rules fails to elaborate on those rules, or simply explains some principles rather than generalize the core system of the principles.

The newly announced Rules clearly defined the ethical principles that should be conformed to in biomedical research:

Informed consent. Respecting and ensuring the rights of subjects to autonomously make their own decision to agree or disagree to participate in research, strictly following the informed consent procedures, prohibiting undue means, such as deception, inducement, threat for

making people agree to participate in, and allowing subjects to withdraw from the research period.

Risk regulation. The safety, health, rights and interests of subjects shall be prior to scientific and social interests. The risk and the benefits of research should be in a rational proportion. The efforts shall be made to make subjects to get maximum benefits and to minimise the harm.

Free of charges and financial aid given. Subjects should be selected on a fair and just basis without any charges, and financial aid should be given as compensation for the reasonable fees paid during the selection.

Privacy protection. The privacy of subjects should be protected. The storage, use and methods for confidentiality of personal information should be disclosed to the subjects and are not allowed for disclosure to any third parties without authorization.

Legal compensation. Subjects involved in the research shall access immediate and free treatment if harmed and get legal and mutual-agreed compensation

Special protection. Special Subjects including children, pregnant women, the mentally retarded and patients with mental disorders should be given special care and protection.

Such laws summarize the principles that should be conformed to in biomedical research involving human subjects and generalizes a relatively complete system of principles with elaboration on every principle, which will enable the public, supervision entities and research institutions to better understand the law and carry out the principles in their practice.

Informed Consent is More Specific and Better Guaranteed

One important task of the ethical review committee for the research institutions is to evaluate if the informed consent of human subjects is fulfilled.

In the past legal documents, the rules for informed consent were over-simple that the operability of law were insufficient, especially in regard to enabling human subjects to make unaffected decisions based on full disclosure of the coming research and its implications on themselves. For instance, Article 17 in the Interim Rules reads: in obtaining informed consent, the applicant shall provide complete, understandable and necessary information to subjects. The informed consent form shall be written in understandable language, and in the minority language and understood by minority people in the case that the research is conducted in the minority areas, and at the same time, subjects shall be given sufficient time to consider whether they agree to participate in the research or not. In this Article, “necessary information” was not defined, leading to lack of a standardized procedure of ethical review.

It has been improved in the Norms on Quality Management for the Clinical Trials of Medial Devices (referred to as Norms below) and the Rules. The Norms specifies that researchers and the designated representatives must fully disclose information including the purpose, process, period, procedures of the test, as well as the possible benefits and risks that human subjects are subject to, and that subject are likely to be distributed into different groups. Meanwhile, researchers should allow subjects to have sufficient time to understand the informed consent form and then decide whether to agree to participate in the research and sign the form.

The Rules also specifies that human subjects should be adequately informed of the following information, including it being a research rather than treatment, the purpose, significance and expected results, possible risks and discomfort as well as possible benefits and implications; whether there is other care or therapy for subjects; confidentiality and

methods ensuring confidentiality, compensation and free treatment in case of harm or damage; subjects should be given enough time to understand the informed consent form before deciding whether to agree to participate in and sign the form.

Liability Subjects and Legal Liability Shall Be Specified in the Management of Ethical Review

Different regulations specify different subjects to conduct ethical review of biomedical research, The Rules specifies that medical institutions conducting ethical review of biomedical research is the liability subjects and shall be responsible for daily management of the ethical review committee and ethical review of biomedical research involving human subjects; It should set up the ethical review committee as required and report to the registry organ within 3 days after establishment.

Ethical review concerns every human subject, and the institutions or individuals involved bear great responsibility. The rights and interests of human subjects will hardly obtain effective guarantee if there is no punishment when the obligations and duties are not fulfilled. In the past, relevant laws only involved the obligations of institutions and individuals but failed to specify the liability. The new Rules has added relevant articles concerning legal liability in its revision. Though the liability is not tough, it is still a big improvement.

In China, the biggest developing country, the protection of human subjects is inadequate, the protection of minors and pregnant women is far from sufficiency, insurance for clinical trials is still in its initial stage, ethical committees in medical institution are running conforming to the standards and the ethical review is not strict. Meanwhile, it is natural for the improvement of laws to take some time. Even the newly announced laws are not perfect, with some problems.

For example, both China Food and Drug Administration (referred to as CFDA below) and National Health and Family Planning Committee have authority over drug clinical trial, and the two bodies enjoy the same status under the central government. Therefore, it might lead to the overlap of executive power of the two bodies and the contradiction of the laws announced by the two bodies.

As the National Health and Family Planning Committee supervise mainly medical institutions, so the Rules targets at standardizing the biomedical research in medical institutions. But, there is also demand for ethical review of biomedical research in colleges, universities and centers for disease control as well as private profit organizations.

Fortunately, the problems mentioned above have drawn attention from legislative branches, and will possibly be fixed in the coming revision of laws. Despite of the problems, we are still confident that China will follow the pace of the international community to further protect the rights and interests of human subjects.

The Method of Estimating the Size of Subjects in Drug Clinical Trials:

(1)The Proclamation of Self-review on the Data of Drug Clinical Trials was released by the official website of CFDA in 28 Aug 2015. The self-review has involved 1622 kinds of drugs to be approved for production or import. Based on the average number of 300 cases required in the third phase of clinical trials, this article estimates that the number of subjects required in ongoing drug clinical trials will total up to around 500, 000.

(2)The statistics released by CFDA of the approved drug clinical trials from 2012 to 2016

shows that the newly approved drug clinical trials within the 4 years reached 1348. Based on the average number of 300 cases required in the third phase of clinical trials, the subjects will exceed 400,000. If other types of clinical trials such as generic drug trials were included, the subjects could have reached 500,000.

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