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Medical research ethics in China

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Medical research ethics has been a growing issue in China over the past two decades. In the 1990s, many relevant documents were translated into Chinese, and many ethics workshops were held in major Chinese research centres. Initially, momentum was generated by the need for ethical review in collaborations funded by international scientific agencies and the drug industry. The Ministry of Health issued requirements for good clinical practice in 1999 (revised in 2003) that also included ethical review. Another factor has been the recent trend toward documentation by ethics committees before publication in international journals. The protection of human participants in international medical research collaborations in China, and in other developing countries, has been a focus of attention in the mass media in developed countries and in the scientific literature. These moves have provided models for ethical implementation[1] and brought attention to the controversies around the protection of participants in clinical trials and observational studies.[2,3] Recently, as research funding from Chinese governmental sources has increased, so also has the requirement for ethical review of domestic research protocols.

Currently, most of the ethical codes for medical research, including the regulations issued by the Ministry of Health in 2007,[4] are based on the principles of autonomy, beneficence, and justice. Autonomy includes situations when consent might be compromised by low literacy or mistaking research for routine health-care services.[5] Justice considerations can arise when large drug-company trials are done in less developed regions (the findings might not be reported back to participants and their communities, or the standard of care in such trials might be measured by domestic rather than global standards).

There are two major criticisms of the principle-based framework in China. The first concerns whether, and how, a framework that focuses on individual autonomy can coexist with a traditional ethic that emphasises social harmony over individual interests. This debate is part of the worldwide critique of ethical imperialism,[6] to which some have responded that principle-based ethics are universal and compatible with other ethical systems[7] whereas others have argued that many medical moralities coexist in all societies.[8] As with virtue-based ethics in developed countries,[9] traditional Chinese ethics focus on relationships and the responsibility of a person to work for the good of others, rather than adherence to general principles of common morality. Some contend that this ethic undermines the protection of individual participants in medical research.[10] However, leading Chinese bioethicists argue that virtues and ethical principles are compatible, and that respect for people, non-maleficence or beneficence, and justice are principles and virtues for a good person.[11] For medical research, major ethical responsibility is placed on the researcher. Thus a signed consent form might be seen less as protection for participants' rights than as a legal

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mechanism that will relieve researchers from their important virtue-based responsibilities. To further the goals of the ethical conduct of medical research, it is essential to continue to clarify how principles and virtues can be used together to enhance the protection of participants.

The second critique takes a broader view of the purpose of medical research ethics, beyond both the function of institutional review boards and their principle-based reasoning, and assessment of actions based on good intentions or achieving good outcomes. Reflecting recent discussions of professional ethics in the context of market reforms,[12] this critique encourages consideration of ethical aspects of the entire research domain, from funding to dissemination of findings,[13] thus capturing the influences underlying economic and social changes within China today and locating potential participants within a broader domain of power and influence. In recent years, economic incentives in medical practice and research exacerbate the potential for conflicts of interest, which can undermine ethical relations between medical professionals and researchers, drug companies, or other research funders, patients who become research participants, and even the regulatory agencies whose mandate is to protect participants' safety. Although forces at play in China might aid advocacy for research participants through the rise of civil society and non-governmental organisations, others might act to undermine essential human rights. The most crucial threat to the protection of human participants in research lies in failing to be aware of and to counteract these dangers. Essential here is maintenance of the independence of ethics committees, and fostering their ability to develop community-engagement mechanisms.

The future looks promising. As China's role in research continues to expand, principle-based ethical review of protocols will become increasingly widespread and standardised. The key issue is not whether, or to what extent, foreign versus traditional ethical theories are relevant in the Chinese context. Rather, it is more vigilant regulation of the business of medical research that is needed to ensure protection of research participants.

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