



Recommendation for Establishing a National Bioethics Commission

Commissioned by the Academic Divisions of the Chinese Academy of Sciences (CAS), a task force headed by CAS Member LIN Qishui recently conducted a study entitled Studies of Bioethical Issues and Advances of Life Science Frontiers. Based on the results of the study, the research team has recommended that a National Bioethics Commission be created under the State Council. The following paragraphs outline the reasons for the recommendation.

Breakthrough developments in the life sciences and gene technology have brought about a series of revolutionary findings. Although those findings have provided unprecedented development opportunities for humanity, they also have introduced risks to society. Such risks call for greater attentiveness followed by appropriate action. An institutional way to address the social risks is to set up a commission on ethical issues.

As the key oversight group responsible for the review and approval of projects, a bioethics body (a board, commission or committee) strives to ensure that research, experiments and healthcare delivery are conducted in a socially and ethically responsible manner. Thanks to the formation of earlier commissions, some of China's groundbreaking research in the life sciences has been applauded by the international academic community, and the instances of misconduct in research and medical activities have been checked to some extent. However, the work of ethics review commissions in different executive departments and institutions is beset by problems, including unclear responsibilities, incomprehensive functions, and a lack of supervision in the examination process. The root cause of the problems lies in the absence of a hierarchical system of ethics commissions, at levels ranging from institutional and regional to departmental

and national. Without a national commission on ethics, in particular, no corresponding policy and supervisory guidance are available, which can lead to a lack of coordination among different functions of the commissions, such as examination, review, arbitration, supervision, planning, training and consultation. Therefore, there is an urgent need to set up a national bioethics commission so as to promote and improve China's management system for bioethical affairs.

I. An Urgent Need to Improve China's Managerial System on Ethics

1. A Need in the Development of the Life Sciences

The development of modern life sciences has accelerated the integration of research with applications in the field, thus giving rise to a special chain of values. Concerns over bioethics have extended from conventional medical issues to larger questions regarding the far-reaching risks to society, such as the possible consequences of developments in the life sciences. Such concerns extend to the allocation or balance of various interests; to what should (or should not) be done, and how to proceed in doing it. The goal of a national bioethics commission is to address the need for a sustainable and healthy development of modern life sciences.

2. As an Effective Measure to Resolve Conflicts of Interest and to Safeguard Sound S&T Policy-making

Controversies over subjects such as transgenes have emerged as a result of the advances of the life sciences and medicine in China; they represent conflicts of value and interest that result from the social application of S&T knowledge, which challenges decision-making concerning biotechnology. By means of democratic deliberation from the S&T perspective, a bioethics commission could help resolve the conflicts and reach consensus among stakeholders, so as to ensure that S&T decisions are made in a scientific and fair manner.

3. As an Effective Guarantee for Standardized Research and Application Management

In many countries a commission on ethics at the national level is one of the important measures for addressing potential risks. International experience shows that such a commission can be an advisory body for national S&T decision-making in terms of ethics, providing guidance for relevant legislation and decision making. By giving full play to its role in supervision, macroscopic management and coordination, the commission can be of vital importance for promoting national S&T development and the application of new technologies.

II. Current Development of Bioethics Commissions

Many countries and territories have established national bioethics commissions to address, at a nation level and in a systematic and sustainable way, a variety of subjects pertaining to ethics in the field of the life sciences, such as policy consultation, policy implementation, ethical oversight and overall consideration of opinions. Studies show that various national ethics commissions have typically adopted the two organizational forms of centralized (such as in the United States and Germany) and decentralized (such as in the United Kingdom) and two forms of functional orientation: comprehensive (such the US President's Commission on Bioethics) and unitary (such as the Danish Council of Ethics). Despite the different histories in these commissions, a consequence of their various functions, the common characteristics for their effective functions are the same: a well-designed legal

system and a specific body of supervision.

Established in the 1990s, China's ethical review system mainly consists of four types of organizations at two administrative levels; and there are regulations concerning the establishment of ethics commissions. The four types of ethics review commissions were set up by governmental departments, regional governments, institutions and academia, each with its own jurisdiction. In terms of administration in ethical issues, and within the two-level management structure, it is institutional ethics commissions that actually undertake the task of ethics reviews. They mainly focus on the ethical review and supervision of biomedical research and relevant technological application within their institutions or subordinate organizations. The ethics commissions established in executive departments and regional governments mainly conduct research, deliberation and policy consultation on major ethics issues, and organize, if necessary, ethics reviews of major research projects. They provide guidance and supervision in the review work of institutional ethics commissions within their jurisdictions.

III. Major Problems with China's Ethics Review System

Bioethical issues have received great attention in China's life science and technology fields. However, the effect of management concerning ethics is far from satisfactory without a national system of ethics commissions and a sound coordination mechanism underlying ethics review and supervision at different levels. Although comparatively speaking, an overall system of ethics review is in the making in the medical field, various problems remain and they require immediate attention.

1. Ethics Reviews Are Not Rigorous and Even become Formalities

Ethics reviews are often not conducted in a rigorous manner; instead, they are often characterized in the following two ways. First, overseas researchers of multicenter clinical drug trails in China are able to make their own choice in selecting Chinese cooperative institutions for ethics review. If their application fails to pass the institution's review, they are able to find a new partner and a new opportunity for review of their



project. Second, research institutions prefer to ask their own commissions to conduct ethics reviews of their projects, and they seldom ask for approval or recordkeeping from concerned administrative departments. Some researchers do not conduct ethics reviews until the completion of experiments, when they are about to publish papers. The review becomes a formality. In addition, there is a confusion of responsibilities in China's ethics review system, in which one institutional ethics review commission has to report to multiple administrative departments for ethics review, such as the National Health and Family Planning Commission, the National Food and Drug Administration, and the State Administration of Traditional Chinese Medicine, leading to both functional overlapping and application uncertainty regarding various disciplines, areas and departments.

2. Lack of an Organization Charged Specifically with Exercising Supervision of Ethics Review Commissions

Many countries in the West have set up agencies to supervise the operation of ethics review commissions. They include the Office of Human Research Protections in the US, the Ethics Committees Authority in the UK and the Central Ethical Review Board in Sweden. Such an organization has not yet been established in China. Instead the institutional ethics review committees are managed by the former Ministry of Health and the former Drug Administration in a macroscopic way. Although there are consultation organizations of ethics experts under the former Ministry of Health and provincial health administrations, they do not have the function of supervising institutional ethics review commissions in their jurisdictions. There is largely no supervision over the operation of institutional ethics review commissions, which leaves the commissions to perform their tasks "in good conscience". In addition, if there is a doubt about the ethics review or if different commissions have different review opinions, there is no supervisory organization to evaluate or settle by arbitration. Therefore, it is difficult to control the quality of the reviews.

3. Rudimentary Operation Process and System of the Ethics Review Commissions

There is no standardized operational process for ethics review commissions in China. The systems for registration, authentication and supervision of ethics

review commissions are often unsatisfactory. The understanding of the importance of ethics review is weak in many fields. Without unified standards, the decisions of ethics review commissions can be loose and less than objective. The different standards of various ethics review commissions make it difficult to protect the rights and welfare of human subjects participating in research and difficult to assess the performance of ethics review commissions.

4. Lack of a Legal Guarantee for Ethics Reviews

All of the regulations and policies concerning the review of ethics in human-related biomedical research, drug clinical trials, medical instrument clinical trials and special technology are generated by executive departments. The documents they provide are the only legal guidance for specific fields, in the absence of any national ethics review legislation bill. In addition, there is no reasonable establishment of functions (such as examination, arbitration, supervision, training, consultation and planning) of ethics review commissions at different levels and in different categories.

IV. An Urgency to Establish a National Ethics Committee

The primary reason for the unsatisfactory state of bioethics management is the lack of a national bioethics commission to perform unified administration. Without such a commission it is hard to achieve a standardization of the basic rules of bioethics, to formulate a general principle for local and institutional ethics review commissions to follow, and to conduct consultation and assessment service for major decision-making concerning ethical issues.

A national bioethics commission is an important part of the sound legal system of a responsible country. The establishment of such a commission will promote research into the ethics of biotechnology and gene engineering so as to provide guidance in research and application in relevant fields; at the national level, it can have a supervisory and management role. In addition, the commission could participate in the formulation of international ethics standards on behalf of the nation, presenting national interests and responding to international concerns.

The following recommendations are made based on international experience and China's situation.

1. Setting up a National Bioethics Commission under the aegis of the State Council

There is a need to establish a National Bioethics Commission at the Legislative Affairs Office of the State Council or the Research Center of the State Council so as to coordinate bioethics affairs in different fields and departments across the country. China's basic research, translational research and clinical application development in life and medical sciences concern multiple jurisdictional areas of several departments. Stem cell studies, for instance, are carried out by different institutions such as institutions of basic research, translational research and clinical application. Among them, some are public institutions under the jurisdiction of several different departments, and others are private organizations. It is necessary to set up a national ethics commission reporting directly to the State Council.

2. Setting up a National Bioethics Commission as a System of Different Sub-commissions

It is advisable to organize the National Bioethics Commission (NBC) as a system of sub-commissions so as to provide effective support, guidance and consultation to China's standardized management of bioethics. As bioethics covers a wide range of areas, it is necessary to set up sub-commissions under the national commission, focusing on a variety of different topics such as genetic resources, experimental animals, clinical research, stem cells, nanotechnology, synthetic biology, and food safety. The NBC should be a permanent organization with its sub-commissions set up according to specific circumstances. At the same time, ad hoc task forces could be created as needed.

3. A National Bioethics Commission with Multiple Management Functions

As to its functions, the NBC should exercise the multiple roles of management.

(1) Major functions are promoting legislation and policy enforcement, ensuring that the concerned research and application development follow social ethics, and

facilitating international cooperation in related fields.

(2) Major responsibilities are advancing ethical studies of topics that merit concern; identifying and scrutinizing problems that might go against the ethical, legal and social norms; promoting legislation in relevant fields and seeing to its implementation and enforcement; and advocating good practices.

(3) Major tasks are providing service to decision-making on major ethical issues; offering consultation services on S&T ethics; formulating a code of practice and general principles for ethics review commissions at different levels; communicating relevant legislative and ethics information to the public and guiding the public in attending related discussions; and seeking international collaboration with commission counterparts in other countries.

To give full play to these functions of the commission, it is necessary to include as members of the commission a percentage of S&T experts such as life scientists and medical experts as well as legal experts, psychologists, policy researchers, administrators and representatives from social organizations. It is recommended that the term of the commission members be five years.

4. Exploring and Establishing a Management Mechanism between Ethics Review Commissions at Different Levels

A clarified supervisory organization is the basis and guarantee for coordination of supervision at various levels and in different departments. The State Council supervises the National Bioethics Commission. Following the establishment of the Commission, it is necessary to improve ethics review commissions at different levels and to improve the ethics management mechanism between commissions at the same or different levels. There is a need to explore the establishment of a network connecting ethics review commissions under different departments and ethics review commissions in different regions so as to provide an overall direction, consultation and service to institutional ethics review boards and to form a clear hierarchical system of supervision.