



Challenges regarding the Research Ethics in China

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The Current Status of the Ethics Committee in China

- ❖ Since the establishment of the Ethics Committee of the MOH in 1998, under the leadership and the support of the Ministries, with the drive force of scientists, ethicists, social and legal societies we are trying to catch up with the International Bioethics process ; The Ethics Committee regularly study the major bioethics issues, relevant policies and regulations; In the last few years, the MOH Medical Ethics Experts Committee conducted three National Ethics Workshop and Training Courses for the Provincial and Municipal, which was organized by the Science and Education Department of MOH,

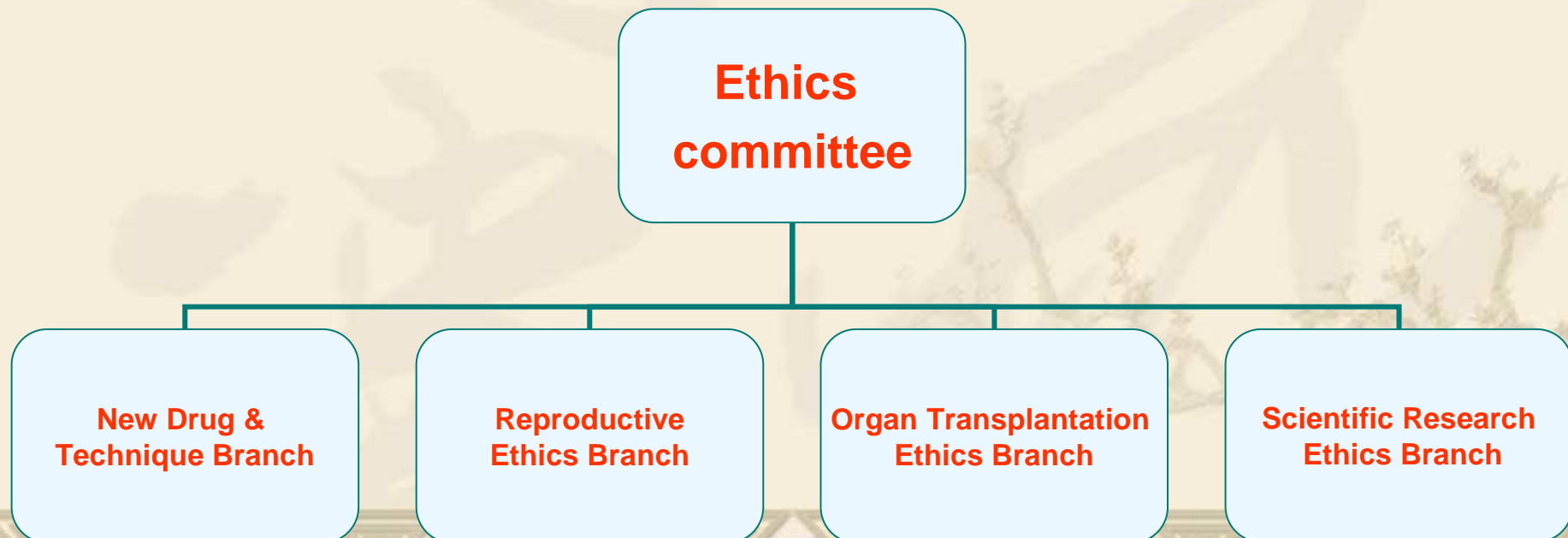
The Current Status of the Ethics Committee in China

- ❖ There are 23 Provinces 5 Autonomic Regions and 4 Municipalities in China , only about half have set up the Provincial Ethics Committee some of them are at the planning stage;
- ❖ According to a survey of 2005, there were 335 Ethics review committees had registered with the State Food and Drug Administration; and it was estimated more than 400 hospital and research institutes had set up Institutional Ethics Committee in China, (According to the statistics report of Ministry of Health in 2008, the Level 3 Class A Hospital in China was 722) ;

Institutional Ethics Committee

- ❖ There was lack of a harmonized system to monitor and supervise the ethics review on medicinal and research work, They are too busy in deal with the daily requirements. Ethics committee in some prominent hospitals and institutions have to set up sub-committees. (As the following chart shows)

Settings of Some Ethics committee in Hospitals



(1) Lack Guidance and Supervision

- ❖ As half of the provincial and autonomous region their steering consulting installations have not in place, the institutional ethical committees at lower levels, were lack guidance and supervision.
- ❖ Among most of the ethics review, the ethics review on drugs and medical devices, as well as reproductive health are comparative up to the nom ; However the multicenter study on biomedical research, reflect the different standards among those institutional ethics committees.

(2) Qualification of Ethics Committee

- ◆ **Though some committees have been established, but lack of qualified members; lack of systematic training before they are appointed, and continuous education.**
- ◆ **How to deal with conflicts of interest?**
 - ❧ Director of Ethics Committee is also the head of the institution;
 - ❧ Conflicts of interest with the committee member;
 - ❧ Investigator is also the Physician in charge of the subjects;
 - ❧ Being a rubber stamp, the independence of some ethics committees has been challenged
- ◆ **Is Ethics Committee required to be certificated or accredited?**

(3) Operating of Ethics Committee

- ◆ **Approved projects have no regular traces and follow-up, and adverse effects of clinical researches were not reported;**
- ◆ **Lack a unified SOP, With a joint effort The Shanghai Medical Ethics Society had just published a draft SOP Dec 2010, whether it will be adopted by all the member?**
- ◆ **How to guarantee the expenditure resource of the EC and its normal functioning.**

(4) Issues Related to Informed Consent

- ◆ In the test group usually avoid to mentioned the important and detail of the risks or keep silent about major risks
- ◆ In the control group didn't explain what is placebo
- ◆ Staff usually not give enough information about other effective methods of treatment and medicine in addition to the drugs of test and control group

(4) Issues Related to Informed Consent

- ❖ No details of the procedure were given: for example, the volume and frequency of blood sample will be taken, how many times of inspect and what is the interval of interview etc.;
- ❖ Didn't emphasis enough that subject could withdraw at any time with no reason; and withdraw will not get any discrimination;
- ❖ In case of bad or serious reaction, avoid mention any "Compensation" or make it very vague;

(4) Issues Related to Informed Consent

- ❖ In Multi- Center study the implementation of GCP and Informed Consent were differ from each other ;
- ❖ Lack of standardization in sign the informed consent form;
 - ❧ Direct translate from the foreign language, not conform with the Chinese Custom;
 - ❧ Patients or subjects didn't have time to carefully read the materials;
 - ❧ Patients or Subjects didn't have chance to put questions

New Challenges

◆ Multicenter study:

- ⌘ During the process of the globalization, with the development of biomedical science in China, China has become the emerging sites. The data has shown the increasing numbers of the registered international clinical trials in China. Since 2008, has been increased by 80% annually;
- ⌘ The quality in ethical review is closely related to the quality of the clinical research. The review capacity varies among different EC in China and there is still distance to meet the requirement for the collaboration review model in Multi-center studies.
- ⌘ Institutional Ethics Committee VS Central Ethics Committee

New Challenges

- ◆ Lack experience involving vulnerable groups such as the clinical trial on pediatric medicine — an issue of global concern; psychotic patients and persons without the capacity to consent.
- ◆ How to handle the 35th item of The Declaration of Helsinki, the “Renovative medicine”, and the clinical application of Category 2 and Category 3 medical technology as classified by MOH.
- ◆ The Ministry of Health had organized several working groups to study What is Renovative Therapy? Who makes the decision?



Thank You !

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