



## **The Current Status and its Challenge of the Ethics Committee in China**

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# I The Development of Biotechnology and the Bioethics



- ❖ As it was indicated by UNESCO on the Bioethics :  
“Stem cell research, genetic testing, cloning:  
progress in the life sciences is giving human beings  
new power to improve our health and control the  
development processes of all living species.  
Concerns about the social, cultural, legal and ethical  
implications of such progress have led to one of the  
most significant debates of the past century. A new  
word has been coined to encompass these concerns:  
bioethics.”
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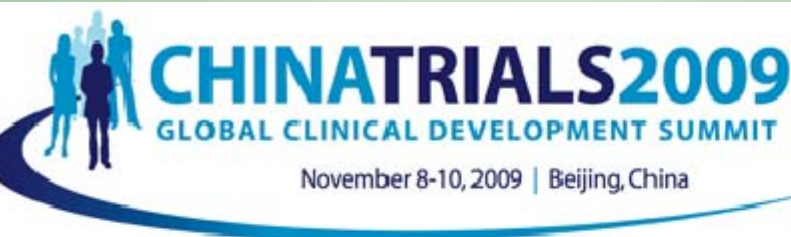


- ❖ With the development of biomedical research in China, the impotent of Ethics has gradually given more attention. Since the 70's of the last century with the application of life-sustaining technology (cardiopulmonary resuscitation), assisted reproductive technology, tissues and organ transplantation technology, stem cell research and application, human genome sequencing, genetic testing biobanking and personalized medicine etc. raised a lots of debate on ethics issues, and a series national and international symposium and conference were organized to discuss the biomedical development and its social, cultural, legal and ethical implications; all of these prompted the ethics development in China;
  - ❖ With the economic development and the opening policy in China, research and development of new pharmaceutical products in our country has become the focus of global interesting. In the last two consecutive years, the Global Clinical Development Summit 2008 and 2009 were organized in Shanghai and Beijing:
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- **China Trials 2008 - Global Clinical Development Summit, was the first time that it brought together global pharmaceutical industry, biotech and CROs for a Industry seminars and exhibitions in Shanghai**
  - **The cost of conducting early phase trials in China can be as low as 15-25% of the cost of conducting similar trials in the West. This has drawn the attention of many emerging biotech companies.**
  - **But cost savings is not the only major driving force for China's clinical industry. The patient population is large and treatment-naïve, enrollment is fast, and the sheer size of the potential future market in China is very attractive for drug makers.**
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# Global Clinical Development Summit

## Nov. 8-10 Beijing



November 8-10, 2009 | Beijing, China

Presented by  
**Lychee Group**

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## YOUR GATEWAY TO CONDUCTING CLINICAL TRIALS IN CHINA

### Regional Coverage of North Asia

If you're looking to China as part of your global clinical strategy, you will no doubt have interest in learning how China fits into a regional strategy. Japanese-Chinese bridging studies, simultaneous development for North Asia, and a comparative look at each Asian country will be addressed.

### Unprecedented Speaking Faculty

With over 75 speakers, we have assembled the largest China clinical speaking faculty ever. Draw insights from top clinical experts representing over 45 of the world's largest pharmaceutical and biotech companies now operating in China.

### Network With the World

Create new global partnerships with hundreds of clinical development executives from the US,

### Beyond Just Outsourcing

The conference agenda goes well beyond just outsourcing topics. If you're one of the hundreds of companies already doing trials in China, we have developed the most comprehensive agenda that will help you improve your current clinical operations with information you will be able to apply to your operations immediately.

### Business AND Science of China Trials

The 2009 agenda features the most advanced discussion on the scientific side of conducting clinical trials in China. Biomarker Development, Personalized Medicine, Clinical Modeling & Simulation, and Biostatistics/Biometrics will all be covered in-depth.

### Find the Right CRO For You

Every major multinational and local GCP & ICH-compliant CRO with operations in China and Asia-Pacific will be

### Quick Links

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- [View the Latest Program Agenda](#)
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### Message of the Week

#### Attendance is up 40% this year!

Don't miss your chance to attend this year's largest China/Asia-focused clinical event. [Register Now!](#)





- ❖ Aug 28, 2007 an analysis by the Financial Times according to data on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), one of the most comprehensive websites where researchers register their studies, shows that China has 274 clinical trials under way, compared with 260 in India. China has overtaken India as one of the fastest-growing locations for drug trials,
  - ❖ At the BIONET-China Workshop on Clinical Trials in Xi'an 2008, Prof. Nikolas Rose BIOS(\*) Centre, London School of Economics, UK pointed to three different sets of factors that make China an attractive country to carry out clinical trials:
    - 1) large population,
    - 2) good medical and research infrastructure at substantially lower cost, and
    - 3) growing domestic pharma market
  - (\*) BIOS is an international centre for research and policy on social aspects of the life sciences and biomedicine.
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- ❖ **With its richer genetic resources of plants, animals and human ethnic groups, China will become the biggest laboratory for biotechnology; China should make a contribution to human health and well-being;**
  - ❖ **China should develop and strengthen its bioethics regulations, ethics is not to make restrictions on the development of technology, but to escort;**
  - ❖ **Technology is a double-edged sword we should protect our genetic resources, protect our people and also protect our scientists.**
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## II The Purpose of this Symposium








❖ In view of this, we host this high-level international ethics symposium in Shanghai, and hope it will provide a platform for the medical professionals and scientists, to explore ways of establishing and improving the ethics review system for biomedical research; more effectively protecting the dignity, rights, safety and well-being of the research subjects; and to setup more comprehensive and appropriate bioethics regulations, let our scientists to follow the code of conduct with more credibility, more productivity and getting more support from public, thus will facilitate further development of science and technology.

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### III The Establishment of the Ethics Committee in China and its Current Status



**“seek harmony without uniformity—  
Bioethics ‘ International and National  
Characters ”  
Is the basis of the core values of  
Global Ethics**

# **The Establishment of Ethics Committee, Ministry of Health**



- ❖ **In 1998 a draft Regulation on Ethical Review of Medical Research Involving Human Subject was drafted, but it was failed to be endorsed, because of controversy, with all the efforts the Regulation was finally announced by the Ministry of Health on Nov. 11 2007;**
  - ❖ **The Ethics Committee of the Ministry of Health ( or we call it The Medical Ethics Experts Committee) was established in 2000.**
  - ❖ **For 10 years a serials of Ethics Guidelines, Regulations and Rules were set up and announced by the Ministry of Health, Ministry of Science and Technology and the State Food and Drug Administration.**
  - ❖ **The development of our Ethics Guidelines, Regulations and Rules were based on our national laws, social system , cultural background, custom and practice with reference to the international ethic principals.**
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# Ethics Guidelines and Administrative Practice on Biomedical Research and Medical Technology



- ❖ **Interim Administrative Measures on human genetic resources (MOST/MOH 1998)**  
Will be updated soon as Regulation on Human Genetic Resources (The draft is under review)
  - ❖ **SFDA--Good Clinical Practice (SFDA 1999-2003)**
  - ❖ **Basic Standards for Human Sperm Bank and Technical Guidelines (MOH, 2001-2003)**
  - ❖ **Technical Guidelines for ART(MOH, 2001-2003).**
  - ❖ **The Ethics Guiding Principal for ART and Human Sperm Bank (MOH 2001- 2003)**
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# Ethics Guidelines and Administrative Practice on Biomedical Research and Medical Technology



- ❖ The Ethics Guiding Principal for Human Embryonic Stem Cell Research (Dec 2003 MOST/MOH ,).
  - ❖ Interim Provisions for Clinical application of human organ transplantation ( July 1 2006 MOH )
  - ❖ Regulations on human organ transplantation (May 1, 2007, State Council)
  - ❖ Regulations on Ethic Review for Biomedical Research Involving Human Subjects (Interim) (Jan 2007 MOH)
  - ❖ Administrative Practice for Clinical application of medical technology, (March 2009 MOH )
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# Reference to the Relevant International Ethical Guidelines



- ❖ The Nuremberg Code (1947)
  - ❖ Declaration of Helsinki (WMA 1964 -2008);
  - ❖ International Ethic Guidelines for Biomedical Research Involving Human Subjects (CIOMS 1982-2002)
  - ❖ Universal Declaration on the Human Genome and Human Rights (UNESCO 1997)
  - ❖ The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research (Department of Health, Education, and Welfare USA. 1979)
  - ❖ ICH-Good Clinical Practice (ICH International Conference on Harmonisation 1996-2002)
  - ❖ Operational Guidelines for Ethics Committees That Review Biomedical Research (WHO/TDR 2000)
  - ❖ *Genomics and World Health* (WHO 2002)
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# Reference to the Relevant International Ethical Guidelines



- ❖ **Ethics, access and safety in tissue and organ transplantation: Issues of global concern (WHO 2003)**
  - ❖ **International Declaration on Human Genetic Data (UNESCO 2003);**
  - ❖ **Universal Declaration on Bioethics and Human Right (UNESCO Dec. 2005)**
  - ❖ **UNESCO—**
    - Guide 1 Establishing Bioethics Committees; (UNESCO 2005)
    - Guide 2 Bioethics Committees at Work Procedures and Policies; (UNESCO 2005)
    - Guide 3 Educating Bioethics Committees; (UNESCO 2007)
  - ❖ **Report of the International Bioethics Committee of UNESCO (IBC) on Consent (UNESCO/IBC 2008)**
  - ❖ **In the development of our ethics Guidelines and Regulations, We also make reference to EURO and other countries guiding principals for example the Euro, Japan US :ICH-GCP, The International Society on Stem Cell Research (ISSCR) and UK related to the Guidelines for the Conduct of Human Embryonic Stem Cell Research etc.**
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# Comparison of China and the ICH's GCP



(Ref : [http://www.cncro.com/newsdetail\\_4931.html](http://www.cncro.com/newsdetail_4931.html) )

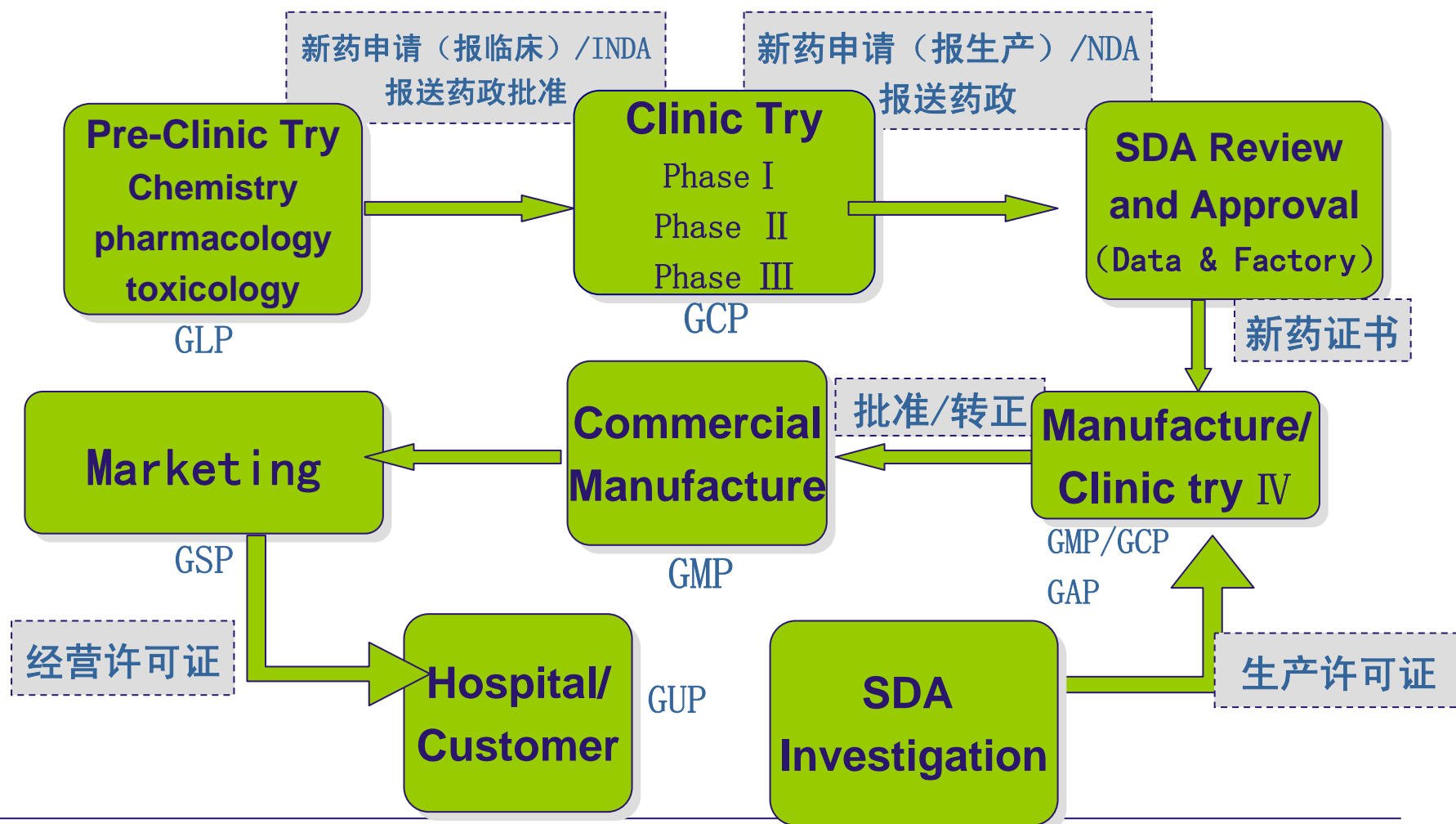
## SFDA-GCP

- ❖ To conduct clinical trial, must obtain the written consent of SFDA Drug Administration Department
- ❖ Clinical trial must be conducted in the institute, which was approved by SFDA, non-medical institute not allowed to conduct clinical trial involved human subject
- ❖ IRB/ECC composition
  - ❖ 1. At least 5 person,;
  - ❖ 2. Should have non-medical profession ;
  - ❖ 3. Should have some member from other institute ;
  - ❖ 4. Member who participate clinical trial have no voting right,
  - ❖ 5. Member should have both Sex
- ❖ Principal investigator must be qualified medical doctor,
- ❖ Only a simple description at the researcher's manual
- ❖ Keep test data at least 5 years

## ICH-GCP

- ❖ Without making provision
- ❖ Without making provision
- ❖ IRB/EC composition
  - ❖ 1-4 same as SFDA-GCP
  - ❖ 5. No specific requirement
- ❖ Without making provision
- ❖ Details description in researcher's manual (Including pharmacology, efficacy, safety, market experience etc.
- ❖ Keep test data at least 2 years.

# Relevant regulations and procedure related to R & D for new medicine in China



# The 6 Good Practice in Medical Products Process



## ❖ The 6 P :

- Good Agricultural Practice-GAP;
  - Good Laboratory Practice -GLP;
  - Good Clinical Practice -GCP;
  - Good Manufacturing Practice-GMP;
  - Good Supply Practice - GSP;
  - Good Use Practice- GUP.
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# Regulations on Ethics Review for Biomedical Research Involving Human Subjects (Interim) (Jan 2007 MOH)



- ❖ **A total of 5 Chapters , 30 Articles**
  - ❖ **Chapter 1, General Principals with 4 Articles;**
  - ❖ **Chapter 2, Ethics Committee with 9 Articles Define the ethics committees at all levels of organization, responsibilities and its authorities, etc.;**
  - ❖ **Chapter 3, Review Procedures with 10 Articles: related to ethic principals, the content, the procedure and the decision etc.;**
  - ❖ **Chapter 4, Supervision and management with 6 articles ;**
  - ❖ **Chapter 5, Supplementary 1 article.**
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# Regulations on Ethics Review for Biomedical Research Involving Human Subjects



- ❖ **Article 4** Ethics review should comply with national laws, regulations and rules, as well as the bioethics principals commonly recognized, and the ethics review should carry out independently, objectively, fairly and in a transparent manner.
  - ❖ **Article 4-6** Establish three levels of ethics committees
    - Ministry of Health has it Ethics Committee ( Medical Ethics Expert Committee) to study and discuss the major ethical issues and put forward policy advice.
    - Health Bureau at the provincial level set up the Provincial Ethics Committee, to organize and review important research projects and to provide guardians and monitoring ethics review works carried out by the Institutional Ethics Committees in its region;
    - Medical and Health Institutes, Research Institutes. Diseases Prevention and Control Institutes and Maternal and Child Health Institutes will set up Institutional Ethics Committees. Major responsibilities of the Institutional Ethics Committee include the review and monitor of the biomedical research work involved human subjects, application of related technologies carried out by their institutions, Institutional ethics committee should also conduct ethics review as requested by the society, and organize training programmes on ethics.
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# The Current Status of the Ethics Committee in China



- ❖ As it was stated earlier, since the establishment of the Ethics Committee of the MOH, 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; involved in international exchange. At the 6th Global Summit of National Bioethics Advisory Bodies, the Chairman of Committee presented the development of bioethics in China, and it was highly commended by the participates.
  - ❖ In the last few years, the Members of MOH Ethics Committee conducted two National Ethics Workshop and Training Courses for the Provincial and Municipal, Which was organized by the Science and Education Department of MOH,
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# 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 Category 3 A Hospital in China was 722) ;
  - ❖ Among all the ethics review, the ethics review on drugs and medical devices, as well as reproductive health are relatively standardized; However the multicenter study on biomedical research, reflects some controversial among those institutional ethics committees.
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## **IV Challenges and Problems of the Ethics Committee in China**



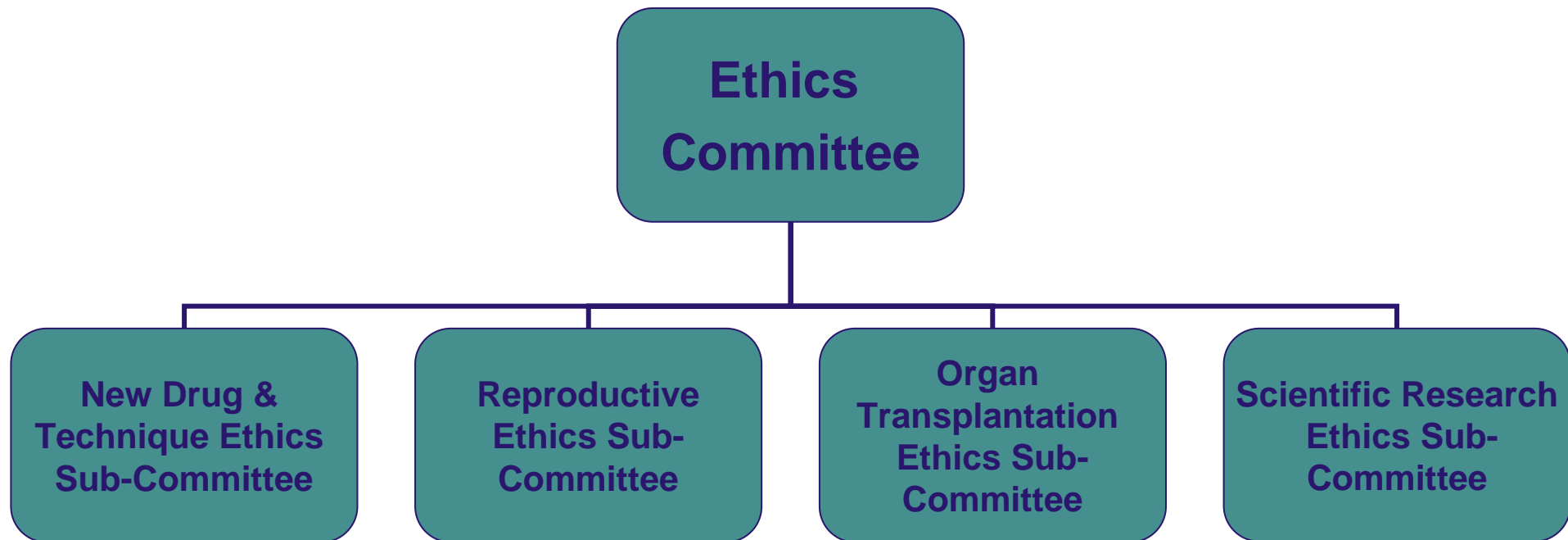
# (1) Re: Setting up of Ethics Committee

- ❖ As it was indicated by the fifth article of the Regulations on Ethical Reviews of Biomedical Research Involving Humans“...Provincial health authorities have their steering consulting organizations of ethics reviews under their administration....Guide and monitor ethical reviews conducted by ethics committees in their administrative areas.” 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.
  - ❖ In those regions which have established provincial or municipal Ethics Committee, however the relevant monitoring and supervising work is just start at its early stages;
  - ❖ Some experts doubted whether all the hospitals and institutions undertaking biomedical research should establish their own Ethics Committee, or a Regional Ethics Committee can be established to take place the work.
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# (1) Re: Setting up of Ethics Committee

- ❖ There was lack of a harmonized system to monitor and supervise the ethics review on medicinal and research work, IRBs are busy in deal with different 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



## (2) Re: Qualification of Ethics Committee



- ❖ Is Ethics Committee required “Recognition” or “Accreditation”?  
By whom?
  - ❖ 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
  - ❖ 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, related to experimental therapy or “Innovative Medical Intervention”, and the clinical application of Category 2 and Category 3 medical technology as classified by MOH.
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### (3) Re: Operating of Ethics Committee



- ❖ Approved projects have no regular traces and follow-up, and adverse effects of clinical researches haven't been reported in time by many IRBs
  - ❖ Many ethics committees have developed SOPs, but they are not and can not be unanimous. Should they be unified and who do the job?
  - ❖ How to guarantee the expenditure resource of the EC and its normal functioning.
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## (4) Other issues need considering



- ❖ In China how to implement the Declaration of Helsinki item 19th on clinical trials registry and the item 30th on reporting and publication of research results? There are over 1,000 medical Journals in China, but up to now only 63 of them have signed the <Chengdu Declaration>, and as memberships with “Chinese Clinical Trial Registration and Publication Collaboration”. Should some of our major medical journal be in response to WHO's and ICMJE's call?
  - ❖ Coordination and mutual understanding in international cooperation.
  - ❖ Ethical issues on experimental animals
  - ❖ Research ethics: the researchers code of conduct .
  - ❖ How to prompt positive interaction between scientists and ethicists.
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## V The Proposed Subjects for this Symposium





- ❖ Status of Ethics Committee and its Challenge;
  - ❖ The Establishment and Evaluation of the Ethics Committee;
  - ❖ Management of the Ethics Committee;
  - ❖ The Standard Operating Procedures;
  - ❖ Informed Consent and Some Special Issues Related to Consent;
  - ❖ The Continuous Training of the EC Members;
  - ❖ Multinational Clinical Trial and Foreign Investigator in China;
  - ❖ International Clinical Trial Registry and Publication;
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## VI Conclusions





- ❖ Biotechnology has experienced rapid development in the last 50 years.
  - ❖ Medical colleagues face with new ethical issues every day such as contraception and abortion, assistant reproduction, prenatal diagnosis, genetic counseling, organ transplantation, terminal care, euthanasia and brain death.
  - ❖ Biomedicine and health research: epidemiology studies, clinical trails, gen assay for genetic screening, intervention trial, and other investigations involving human subjects, etc.
  - ❖ Health policy and management: health resource allocation, medical and health reform, application and management of hi-tech in biomedicine.
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- ❖ WHO, UNESCO, other international institutions and developed countries have developed many relevant principles, guidelines, norms and declarations on Ethics.
  - ❖ Each country has to frame its own ethical guidelines and regulations on its different politics, economics and culture. Modern bioethics in China initiated relatively late, but is gradually improving in recent years. Hope that international experience and guiding principles will play a positive role in promoting the development of Bioethics in our country.
  - ❖ Ethics is not to make restrictions on the development of technology, but to escort. Let us work together to promote the positive interaction between ethicists and scientists, so as to direct science's healthy and orderly development for the sake of all mankind and long-term interests of future generations.
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Issues can not be settled at once;  
this is only the beginning!  
Thanks for all your support and  
participation!

**Thank You !**

**Qingli Hu**