The Development & Expectation of Bioethics in China

Prof Qing-Li Hu

Director, Ethics Committee, Shangai Clinical Research Center

Emeritus Professor, Senior Advisor, Shanghai Jiaotong University

Member of the UNESCO International Bioethics Committee
- Brief Introduction of Bioethics in China

- Ethic Guidelines and Regulations

- Challenges and Collaborations in Ethics Review
II. Brief Introduction of Bioethics in China
The Traditional Chinese Philosophy

- It is China’s fine tradition to attach importance to ethics and morality,
- The Chinese “sage” Confucius once said “仁者爱人” that is “Benevolence means love of people.” He advocated respecting people, concerning about people and caring for people. His saying “Do onto others as you would have them do onto you” this has been widely recognized by the world as the “Golden Rule” of morality.

Confucius (551–479 BC) his name is Kong Qiu (孔丘)
A long history of doctor’s concern

The Chinese Hippocratic Oath: 大医精诚

Dr. Sun Simiao (581 ~ 682)
Modern Bioethics in China

A combination of the Chinese and West philosophy

- Life-Sustaining Tech.
- Assisted Reproductive Tech.
- Transplantation
- Genome Tech.
- Bio-banking

Bioethics
Universal Declaration on the Human Genome and Human Rights

International Declaration on Human Genetic Data

Universal Declaration on Bioethics and Human Right

CIOMS; International Ethics Guidelines for Biomedical Research Involving Human Subjects 2002

WHO: Genomics and world Health 2002


WHO; Review of Ethical Issues in medical Genetics 2003
□. Ethic Guidelines and Regulations
The Establishment of China National Ethics Committee

Nuremberg Code

Helsinki Declaration

The Ethics Committee of the Ministry of Health
(1st, 1998)

CIOMS

WHO/UNESCO
The Current Status of Ethics Committee in China

Three Levels

**Nation**
- China National Ethics Committee

**Region**
- 23 Provinces, 5 Autonomic Regions and 4 Municipalities Government
- 50% set up the Regional or Provincial Ethics Committee

**Institution**
- ~1000 Level 3rd grade A Hospital in China
- > 400 have set up IEC, and 335 had registered at CFDA as the pharmaceutical research bases
Most of IEC at the 3rd level grade A Hospital in Shanghai, They are too busy in deal with the daily requirements for Ethics review. The Ethics committee have to set up several sub-committees to meet it’s needs. (As the following chart shows)

**Settings of Some Ethics committee in Hospitals**

- New Drug & Technique Sub-committee
- Reproductive Ethics Sub-committee
- Organ Transplantation Ethics Sub-committee
- Scientific Research Ethics Sub-committee
Ethics is not to make restrictions on the development of science and technology, but to escort and support its rational development.
 challenges and Collaboration in ELSI
Each country has to frame her own ethical regulation based on politics, economics and cultures, however, an international ethical strategy for huge scope study need to be established such as multi-center study in Pharmaceutical Studies, Genomics Research, Synthetic Biology Research etc;

- How to improve the capacities building of ethics committee's;
- How to follow up research activities;
- How to deal with beneficial share with Cooperator and with Patients or Participants;
- How to provide accurate and proper information to the public and the media;
The Challenges

Angel Biological

(http://www.shabt.com/)

- Make a Gene Sequencing to test Baby’s Character, IQ, Art, Sport and Cognitive Capacity; as well as baby’s Health.....etc..
The Golden Rice Issue

- A 4-year study in Chinese schoolchildren were given golden rice.
- The results of that study, published online early in August, 2012;
- Greenpeace China claimed the trial shouldn't have gone forward and called it a "scandal of international proportions."

A genetically modified form of rice designed to boost vitamin A levels.
China join the Human genome project in 1999, and established ELSI department. 2000 accomplished its task of 1% gene sequencing.

the CENTER will coordinate the major human genome projects in various frontier areas in Shanghai, provide high quality service for research institutions and biotech/pharmaceutical companies at home and abroad, and serve as an incubator of genomic industry in China.
SCRC operates as a 3rd-party full-service assessment and resource center to facilitate drug development. Fully equipped central laboratory with GLP capabilities, a state-of-the-art data management and a bio-statistics system and Independent Ethics Committee; SCRC act as a third party management, backup and coordinator of the Shanghai Disease-Based Biobank, and develop an Ethics Guidelines.

Founded By MST & Shanghai Municipal Govt. in 2008

The Independent Ethics Committee (IEC) at SCRC was established in October 2008
Shanghai Institutes For Biological Sciences, SIBS

- SIBS dedicated to enhancing biological security and safety and reducing the risks of the misuse of the life science.
- Synthetic Biology Project
- China /Austria synthetic biology and biological safety conference Jan 2010 Beijing; Oct. 2011 Shanghai

Established in Shanghai on July 3rd, 1999
BGI in Shenzhen, China

- Beijing Genomics Institute (BGI): BGI is poised to become the biggest DNA-sequencing laboratory not only in China but in the world.

- China National Genebank, collecting biological resources (from animals, plants, microbes, marine organisms and human) & big data, and building a sharing and exchanging platform to promote cooperation and utilization of the resources and information.
The ELSI related projects

- The Ethics Guideline on Stem Cell Research and Clinical Application
- Ethical Guideline on Biobanking
- Case Study on Gene Discrimination in China
To meet the Challenges of Multi-Center Studies

- CFDA 2012 issued “Ethics Review Guidelines for Pharmaceuticals Clinical trial”

- The Chapter 5 Article 31 of the Guideline is particularly focused on multi-center clinical study:
  - (1) IEC of the Leading agency is responsible for review the Scientific and Ethics rationality of the research protocol.
  - (2) IEC of the Participate institutes, reviews the feasibility of this institution in joining this multi-center study, including researchers' qualifications, experience is there sufficient time, staffing and equipment to participate in clinical trials.
– (3) All participate Institute can make suggestion to modify the protocol if needed, a written document should report to the sponsor, consensus should be made to ensure the smooth running of the multi-center study.

– (4) IEC of the participate institute should make a track review in its implementation of the clinical trials. For the safety of the participants, should serious adverse events happened, IEC of the participate institute, should be responsible for the timely review, and entitled to suspend test in their institutions, and report to the leading agency and sponsor.

– (5) Leading agency of the multi-center study should be timely review the track review report and distribute to all participate institutes for record.
Human Genetic Resources Administrative Management Regulation (draft)*

- For protection the national interesting in International Cooperation:

- Equality and mutual benefit, honesty and credit, participation and sharing together;
  - (1) The staff of Chinese Participate Institution should be involved in the joint development activity Article 21;
  - (2) After complete the endorsed international joint research project, submit a report to the relevant Science & Technology Dept. in three months time; Article 27;
  - (3) The Institute using the Genetic resources, should promote the research results be widely served to the public; Providers of genetic resources, shall be given priority in these medical and health products and receiving services. Article 29

* Based on MST/MOH: Human Genetic Resources Administrative Management Interim Measures 1998
“Currently, ELSI research in genomics is carried out across the world in a soloed, parochial, and uncoordinated way – carried out by individuals or small research teams focusing on context-specific concerns that may vary widely between nations and regions.”

It is now the time to based on P3G’s approach to harmonize the international activity in ELSI issues that related to genomic and biobanking programs.

It is not so easy!
Thanks for Your Kind Attention!

Qing-Li Hu