

Activities of the Korean Association of the Institutions Review Boards (KAIRB) in the year of 2002-2003 Korea

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I. Foundation of KAIRB

On September 13, 2001, preparing KAIRB was agreed in principle at a preliminary meeting for the establishment of “The Korean Association of IRBs (KAIRB),” Attendants of the meetings were representatives of the Korean Academy of Medical Sciences (KAMS), the Korean Society for Clinical Pharmacology and Therapeutics, and major IRBs in Korea. November 20, 2001, five representatives of KAMS and three from major IRBs formed a taskforce team for organizing the preparations and procedures. On February 25, 2002, Preparatory Committee for KAIRB was established, which were composed of 42 members from universities, health authorities, academic societies, and media. On March 18, 2002, The Korean Association of Institutional Review Boards (KAIRB) was founded and elected officers.

II. KAIRB and FERCAP

Even before the birth of KAIRB, FERCAP and TDR played an important role in placing KARIB in the international setting and context. On 20-22, 2002 December, WHO TDR organized *International Meeting on Research Ethics in China, South Korea and Japan* in Nagasaki, Japan. Although it was before the foundation of KAIRB, the Preparatory Committee for the Foundation of KAIRB delegated a member to the meeting to present the forthcoming foundation of KAIRB as a national forum for ethics review committees. From the meeting, the forthcoming KAIRB established international and regional collaboration and found rich resources to develop standard operating procedures for research ethics review including WHO TDR's *Operational Guidelines for Research Ethics Review Committees*. From then on, KARIB has delegated a representative to FERCAP annual meetings to promote international communications and to build national capacity for ethics review through the FERCAP resources and meetings. KAIRB's participation in FERCAP activities proved to be crucial for building up in-country capacities of ethics review of biomedical research. Utilizing rich resources and information through international communication in the annual meeting of FERCAP 2002, KAIRB made important advancement in research ethics.

III. Activities of KAIRB 2002-2003

1. March-April 2002: National survey on IRB operation in Korea

The KAIRB performed a survey research on current status of IRBs in Korea. The president of KAIRB (Dr. Shin) published the result. I'll attach the paper and the editorial.

2. May 4th 2002: Symposium on Research Ethics in Korea

The KAIRB held a symposium on Research Ethics in Korea at the 30th Congress of Korean Medical Association (KMA) with following topics:

- 1) Comparison of KGCP with WHO guidelines
- 2) Current situations of IRB operations in Korea
- 3) Future direction of IRB operations

About 160 people from IRBs, academia and industries participated in the symposium and active discussion continued during the symposium among the participants.

3. June 19-21, 2002: Korea-NIH conference on ethical and regulatory aspects of human research

The KAIRB held an international symposium, co-host with Dept. of Clinical Bioethics, NIH USA. Eleven lecturers were invited from USA, European and African countries. Attendants were more than one hundred IRB members, 64 researchers, 37 from industry, 5 from the government.

4. July 25–27, July 29-August 2, 2002: Attending FERCAP meetings and conference:

The KAIRB delegated the Secretary of KAIRB as a representative of the organization to the FERCAP meetings and conference. After participating the meetings, the Secretary reported FERCAP meetings and distributed the new guidelines (the Blue Book) of August 2002.

5. July -September 2002: Conducted "Project for Developing Guidelines for Stem Cell Research and Introduction of IRB System."

Requested by MOST (Ministry of Science & Technology), KAIRB conducted "Project for Developing Guidelines for Stem Cell Research and Introduction of IRB System."

Through the MOST Project, KAIRB provided the MOST with drafted guidelines and recommendations on stem cell research & IRB operations.

- 1) Double check systems for the review of stem cell research:
 - (1) local IRB and (2) Special Ethics Committee for stem cell research
- 2) Set boundaries of stem cell research: ban creation of embryos for research purposes
- 3) Strongly recommended to establish IRBs at every biomedical research institution (currently IRBs exist mainly in clinical trial hospitals)

6. February 2003: KAIRB published "Guidelines for Establishment and Operation of the IRB in Korea" (the KAIRB, Seoul)

Nationwide survey by KAIRB (April 2002) demonstrated that only 30% IRBs reviewed academic researches. Given growing concerns over ethical aspects of biomedical researches such as genomic studies, genetic studies, and stem cell research, the Korean Academy of Medical Sciences released an editorial to urge every research to

be reviewed by EC or IRB (February 2003). Stimulated by FERCAP meeting (July 2002) and spurred by the MOST project (Sep. 2002), KAIRB began to work on the Guidelines for Establishing and Operating IRBs in Korea.

In October 2002 Draft Guidelines were made based upon international and national guidelines, regulations, and ethics codes. Draft Guidelines were circulated for comment. The comment period ended on December 30, 2002. Comments mainly came from IRB members, KAIRB member societies, scientific societies, governmental bodies, and sponsors. In February 2003 the Steering Committee reviewed comments and finalized Guidelines for Establishing and Operating IRBs (in Korean). Soon after, the Guidelines were distributed to IRBs and research institutes nationwide.

Guidelines for Establishment and Operation of the IRB in Korea

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7. February 2003: KAIRB published “Current Status of the IRBs in Korea: Constitution, Operation, and Policy for Protection of Human Research Participants.”

In August 2002, the Korean Academy of Medical Sciences (KAMS) requested KAIRB to publish the national survey on IRBs conducted April 2002 by KAIRB. The survey results were published in the *Journal of Korean Medical Science* (JKMS, Feb, 2003, <http://jkms.kams.or.kr>) as a special article. Referring to the article, the editorial of JKMS emphasized the importance of capacity building for ethics review and responsibility of researchers to be reviewed by IRBs before publication.

8. May 27-28, 2003: KAIRB published organized biannual workshops to train IRB members-"Ethical and Regulatory Aspects in IRB Operations."

KAIRB organized the first KAIRB Workshop on Research Ethics and Regulations for IRB Members on May 27-28, 2003. The first day (May 27) program consisted of basic courses for IRB members; the second day (May 28) was allotted as advance courses to deal with more difficult topics.

Sponsored by governments (MOST, FDA) academia (KAMS, CPT), and industry (KAPM, KAPI), the Workshop has lecturers mainly from members of the KAIRB Education and Training Subcommittee; government officials from FDA, NIH, MOHW; ELSI of Human Genome Project; and the Ethic Committee of Stem Cell Project. Panelists were researchers, sponsors, governments, and IRB members.

Workshop attendants were 138 IRB members and chairpersons of university hospital IRBs, 10 Medical Directors of pharmaceutical industries and CRO, and one traditional medicine hospital. Among all 151 attendants, 122 people came from Cosmopolitan area (Seoul), and 29 from Provinces.

KAIRB Workshop for IRB Members: "Ethical and Regulatory Aspects in IRB Operations."

Program

First day- Basic Course

- 08:50-09:00 Greetings President of KAIRB/ Commissioner of KFDA
- 09:00-09:40 Historical development of IRBs and its Significance in Biomedical Research
- 09:40-10:00 The Trends in IRB Operation : Global Issues
- 10:00-10:20 In-Country Challenges for IRB Operation
- 10:40-12:00 Regulation & Policies Update for Clinical Trials
 - 1. Ethical and Regulatory Changes for Clinical Trials - KFDA
 - 2. Current System of Approval and Management of Biological Material - KFDA
 - 3. Regulation of Review of Functional Food Trials - MOHW
- 12:00-13:10 Lunch

- 13:10-13:50 Sponsor's Perspectives on IRB review
- 13:50-14:30 Basic IRB Review : Principles
- 14:30-14:50 Coffee Break
- 14:50-15:30 Basic IRB Review : Operation and Administration
- 15:30-16:10 Basic IRB Review : Observational Studies
- 16:10-16:50 Informed Consent
- 16:50-17:00 Evaluation

Second day- Advanced Course

- 09:00-09:30 Review for the Researches on Vulnerable Subjects
- 09:30-10:00 Conflict of Interest and IRB operation
- 10:00-10:20 Coffee Break
- 10:20-11:10 Panel Discussion I: Expedited Review
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- 11:40-12:00 Quality assurance program
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 - 1. Building Network of expert secretaries of IRBs
 - 2. Quality Improvement System: OHRP
 - 3. Plan for Future Cooperation
- 13:10-13:50 Emerging Biotechnology and IRB Review (2) Human Genomic Research
- 13:50-14:40 Panel Discussion II: Continuing Review
- 15:00-15:40 Emerging Biotechnology and IRB Review (3) Stem Cell Research including Fetal Tissue
- 15:40-16:00 Evaluation

9. May 27, 2003: KAIRB published a Newsletter

On May 27, 2003, KAIRB published the first Newsletter with following contents:

Contents:

- (1) Briefing of one or two IRBs; history, constitution, operation, current activities, plans, etc;
- (2) News pertaining research ethics review;
- (3) Column: important topics of ethics review;
- (4) International Education Program for Research Ethics;
- (5) Activities and plans of the KARIB.

Currently KAIRB plans to publish the newsletter biannually.

10. KAIRB Future Plans

KAIRB's future plans are as following:

- 1) Strengthening the Network of Expert Secretaries;
- 2) Enhancing international collaboration;
- 3) Providing Workshops to the IRB members in the Provinces;
- 3) Updates Recent Information on Ethics Review to IRB members;
- 4) Provide Q&A services utilizing network of expert secretaries;
- 5) Introduction of QA system.

In summary, many activities related to the research ethics review have been done on by KAIRB since its foundation on March 18, 2002. As a whole, the awareness on biomedical research ethics is elevating both in professional groups and in public in

Korea. And KAIRB has been, and will be playing an important role in advancing research ethics and research review capacities.