

# ***Eubios Journal of Asian and International Bioethics***

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### **Send papers to the editor in electronic form if possible.**

Papers are peer reviewed. More details on the penultimate page, as well as the editorial board and aims of EJAIB. The editor, Darryl Macer is Director, Eubios Ethics Institute; and an Affiliated Professor, United Nations University Institute of Advanced Studies, Japan.

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***The November 2005 issue is being published at the same time.***

**Please note the new edition of the textbook can be ordered and is available. Teachers who wish to try the text can obtain copies for free. Please write to the editor. It has double the number of chapters and topics as the first edition, which it replaces, *Bioethics for Informed Citizens Across Cultures*.**

### ***A Cross Cultural Introduction to Bioethics***

**Editor, Darryl Macer,**

**302 pages, A4 size.**

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## **Editorial: Social responsibility and bioethics**

- Darryl Macer, Ph.D.

UNESCO Bangkok

This issue of the journal comes after the successful First UNESCO Bangkok Bioethics Roundtable, held 11-15 September, in Bangkok. There were nearly 100 papers presented in plenary sessions with active discussion among 150 registrants from 32 countries. The abstracts were published in the July issue of *EJAIB*, and the proceedings including transcripts of the discussions are being prepared to publication early in 2006. The volume will be immense, and will help widen concepts of the research methods and policy actions that can be taken to implement bioethics to the needs of people across the world.

As we develop bioethics in the Asia-Pacific region there is a need for exploring the cultural situation of each country, and conducting in depth analysis of the situation that exists. In this issue of the journal there is a paper by Osemwegie that took one of the methods of descriptive bioethics that have been utilized in Asia and the Pacific by Eubios Ethics Institute in the past decade and applied these to an African context. Whether we use the term opinion poll, survey, interview, etc., the general principle is to seek the views of the population. A mixture of methods is required. The results are interesting in that similar to the surveys conducted in China, Thailand and India in the 1990s, the respondents are enthusiastic towards the adoption of genetic technology. There is a need for policy makers to consider the implications of that enthusiasm, and to set up methods for community engagement and public discussion with an aim as to how to implement the international bioethics declarations agreed to by governments at UNESCO General Conferences in 1997, 2003 and 2005.

The other two papers in this issue also look at issues of needs to countries in the region. The question of externally sponsored research in Japan was surveyed by Bagheri and Macer, and the results show the application of ethical principles to questions of sponsored research. The way that this issue is covered in other countries would be of much interest. The ethics of emergencies is discussed by Hans Martin Sass. In 2006 UNESCO will have some meetings on bioethics and social responsibility, including looking at the responses in recent disasters such as the Tsunami in South East Asia and the earthquake in Pakistan/India.

## Ethics Review of Externally-Sponsored Research in Japan

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### Abstract

This survey has been designed as a multinational collaboration to collect data from several countries focusing on developing countries. The main purpose was to elaborate the functions of ethics committees regarding externally-sponsored research (ESR). In March 2004 a total of 89 open-ended questionnaires were sent to ethics review committees (ECs) in medical schools, medical research institutes and hospitals affiliated to the public and private medical universities in Japan.

Twenty two ECs replied (25%), and among them five ECs had reviewed eleven ESR proposals in 2002-3. Five of those ESR proposals have been approved and four proposals have been approved after some revisions. Two proposals were deferred but not resumed. In their review, respondents were more concerned about "individual consent" than "community consent". Post-trial access to effective interventions was not a real concern. As for "Standard of care", seven ECs replied that they review the ESR proposal based on the international standards and four based on the local standards. Whether ESR proposal is matched with the national health priorities was not a great concern. Respondents expressed their concern about socio-cultural issues.

Ethics in research especially dealing with externally-sponsored research is a relatively new subject and under development in Japan. Although Japan is not a developing country, in order to protect individual human subjects and local community, capacity building in ethics review especially in research collaboration with other developed and developing countries is crucial and it has to be included in ethics in research programs through out the country.

### Background

In developing and developed countries alike, biomedical research is an essential component of improving healthcare. An emerging issue is that many developing countries have been targeted as host countries for clinical trials on human subjects which might not be conducted in developed countries because of various factors such as: the cost of research, accessibility of human subjects, lack of compensation policy, ease to get acceptance from local ethics committees in host countries, particular population attributes, e.g. genetic and/or ethnic factors. Obviously in any collaboration the fear of exploitation will undermine a constructive effort particularly in less powerful developing countries.

Several international ethical guidelines have been issued by some international organizations to address the issue of externally-sponsored research particularly in developing countries [1]. In practice on the one hand applying these guidelines is often fraught with difficulty and some times provide conflicting advice [2]. On the other hand the current

situation in different countries in terms of how they deal with ESR proposals has not been documented.

In 2004 a survey has been designed by authors and some other colleagues in different countries, as a multinational collaboration to collect data from several countries (focusing on developing countries). The aim was to elaborate the functions of ethics committees regarding externally-sponsored research (ESR). In Japan the so-called "Millennium Project", a genome-wide association study on five common diseases (dementia, cancer, diabetes mellitus, hypertension, and asthma), lunched by the Japanese government in December, 1999 was a reminder to the necessity of ethics committees in Japan. Earlier reports had found a gradual development of ethics committees in Japan. Since there have been no official guidelines to deal with ethical issues in genetic researches, the Japanese Ministry of Health, Labor and Welfare (MHLW) appointed a special committee to develop ethical guidelines [3]. Accordingly in March 2001, "Ethics Guidelines for Human Genome/Gene Analysis Research" was issued jointly by three Ministries (the Ministry of Education, Sports, Science and Technology (MEXT), the MHLW, and the Ministry of Economy, Trade and Industry (METI)). In June 2002, "Ethics Guidelines for Epidemiological Studies" has been developed by MEXT and MHLW. According to these ethics guidelines, every research institute and hospital which intended to conduct genomic research involving human subjects is required to establish an ethics review committee. When these ethics guidelines were issued, it was implicitly premised on the condition that research institutes and hospitals had set up their own ethics review committees and these committees could fulfill their rolls properly. A nationwide survey by Shirai and colleagues showed that among the research institutions in Japan, 32% set up one ethics committee, 15% had two or more ethics committees with different roles, and 7% were preparing to set up an ethics committee. However, 47% of the research institutions had not established any ethics committees [4].

This paper highlights how surveyed ethics review committees deal with externally-sponsored research. By doing so the paper presents the recent statistics of ESR proposals in Japan.

### Methods

The questionnaire was designed to evaluate the ethics review committees in three dimensions: first, the status of those ethics committees, second the function of ethics committees to review externally-sponsored research, third the current statistics of externally-sponsored research in Japan. The issues such as: the composition and function of ethics committees, the number of research proposals, suggested by an international organization, foreign research institutes or individual researches, and the points which ECs take into account in reviewing ESR proposals and other relevant issues.

A total of 89 open-ended questionnaires were sent to ethics committees by mail. The target institutions in this survey were medical schools, medical research institutes and hospitals affiliated to the public and private medical universities who have already established ethics committee [5]. The survey was carried out between March and April, 2004. Twenty two ECs have been replied (a response rate of 25%) which include seventeen ECs in public and five private universities. Five ECs have been reviewed eleven externally-sponsored research proposals. As for the status of Japanese ethics committees in general, authors also refers to some other published data.

**Table 1: Degree of concern while reviewing an Eternally-Sponsored Research Protocols**

The Points taken into Account by ECs in Reviewing ESR Proposals (The Degree of Concern)	<i>Always</i>	<i>Sometimes</i>	<i>Seldom</i>	<i>Never</i>	<i>No answer</i>
Whether research topic is one of the health priorities of the country	1	0	5	4	12
Scientifically sound and reliable research methodology	11	0	0	0	11
Respecting social and cultural issues	10	1	0	0	11
Compensation to the subjects	2	2	3	3	12
Post-trial access to effective interventions	2	4	2	3	11
Observance of justice in subject selection	10	1	0	0	11

**Table 2: Ethics Review Based on Local and International Standards**

Decision in accordance with	Local Standards	International Standards	<i>Both</i>
Standard of Care	4	6	1
Minimizing the risks	6	4	1

**Table 3: Number of Externally-Sponsored Research (ESR) reviewed by the committee in 2002 and 2003, and results**

ESR Proposal	2003
Approved	5
Approved with conditions and changes	4
Rejected	0
Deferred but not resubmitted	2

**Table 4: Kinds of Collaborations**

Collaboration	Multi-national	Bilateral	Kind of Collaboration			
			Sample collection	data analyzed in Japan	data analyzed abroad	with capacity building
Approved ESR proposals	1	8	5	7	1	0

## Results

### Status and the Function of ECs in Reviewing Externally-Sponsored Research

In all ECs membership is for two years each term. There is a payment system for external experts who are invited for a meeting. Only two ECs in private universities have included religious experts and twelve ECs who replied had lay persons in their membership. Participation of female representatives has been emphasized by three ethics committees. No previous experience is required but the committees provide material for self-training. Half of the respondents are always concerned whether the research methodology is scientifically sound and reliable. Among respondents, five ECs have had all members trained for their job while in three ECs none of the members were specially trained. Another six ECs have some trained members for their job.

"Individual consent" is an issue which nine ECs take into account while reviewing an ESR proposal and four ECs shows concern about "community consent" and eight ECs are concerned whether informed consent is always documented in writing. Six ECs responded that they are also concerned whether any effort is made to ascertain that the subjects actually comprehend the research process. In their assessment of the risks to the subjects and benefits to others (society) five ECs gave priority to "avoiding harm to the subjects" while two ECs gave priority to the benefits of society. As seen in Table 1, only one EC replied that in their ethical review they are "always" concerned whether the suggested proposal is matched with the national health priority, while five ECs are "sometimes" concerned; four ECs said they were

"never" concerned about this issue in their ethical review. Regarding cultural issues, of eleven respondents, ten ECs replied that in their ethical review they "always" take into account cultural and societal beliefs and one EC chose "Sometimes".

As it is shown in Table 2, regarding "Standard of care" seven ECs, review the proposal based on the international standards (best available care in the world), and four ECs review ESR proposals based on the local standards (best available care in the country). Decision about the minimizing the risks, four ECs replied they decide based on international standards and six ECs decide based on the local standards (Table 2). Asking about the necessity of compensation to the subject, among ten ECs who replied, three ECs chose: "Seldom", two ECs: "sometimes", two ECs "always" and three said they "never" take it into account in their review. Regarding the necessity of post-trial access to effective interventions (the availability of the research products to the local community), two ECs said they "always" considered it an important issue in their review, four ECs replied "sometimes", two ECs "seldom" and three of them "never" consider post trial access as a responsibility of the researcher or research institute. Whether it is necessary to be concern about "justice in subject selection" in the ESR proposal, ten ECs replied they have emphasized on it and one EC said they are "sometimes" concern about this issue.