Institutional review boards, worldwide (IRBs)

Institutional Review Boards, Worldwide (IRBs)

- Jayapaul Azariah, Ph.D.
Founder President, All India Bioethics Association,
New No. 4, 8th Lane, Indiranagar,
Chennai 600 020. India
Email: jazariah@yahoo.com

Abstract

The concept of Bioethics Committees evolved due to mistreatment of human beings during the periods of war as well as to find a medical treatment-cure for syphilis in the USA. Bioethics committees address ethical and moral issues raised due to the advancement of science and technology in the fields of Life Sciences, Biosciences and Medical Sciences. There is also a need to develop a mechanism to address ethically burdened issues and provide an impetus to governments and policy makers for ethical governance. Such a body which provides such logistic mechanism goes by the umbrella term of Bioethics Committees. Bioethics Committees have taken various dimensions such as Institutional Review Boards (IRB), Research Ethics Committee, National Bioethics Advisory Committee, Policy-making Bioethics Committee, Hospital and Health Care Bioethics Committee and Medical –Health professional bioethics Committees. An analysis has been made to record the number of countries which have IRBs – out of a total of 245 countries. A few countries have more than one hundred IRBs and about 99 countries have no bioethical committees. Special attention has been paid to Indian national scenarios, and case studies of YRG Care and ICMR are discussed. The need to address upcoming biotechnological issues in Asian countries, in the context of IRBs, has been pointed out. The importance of recognizing medical ethics and bioethics as academic disciplines has been pointed out.

Introduction - Historical

It is well documented in eastern literature that rudiments of medical ethics existed from the early civilization of the Vedic Period (3000 - 800 BC) (Azariah 2003). However, modern medical ethics and the broader discipline of Bioethics *per se* take their roots from western biomedical and behavioural sciences as well as from western philosophy. Following historical situations provided the ground and formed the compelling reason for the institution of Institutional Review Boards (IRBs). The German-Nazi doctor's inhuman experimentation and mistreatment of prisoners during World War II resulted in the emergence of Nuremberg Code in 1947. The UN brought out the Universal Declaration on Human Rights (UDHR) in 1948.

The Tuskegee Report deals with the case of male Negro (1932-1972) in Tuskegee Alabama. About 399 and 201 healthy human subjects, without syphilis, constituted the control group. These human subjects formed a part of an experiment to find out a treatment-cure for the disease. The research subjects were kept in total darkness as to the nature of the treatment and they were not given the choice to be enrolled in the study (no informed consent). As a result the Tuskegee Syphilis Study came to be known as the "arguably the most infamous biomedical research study in US History".

The Belmont Report was published in 1978 by the US Department of Health and Human Services, explaining the unifying bioethical principles aimed at the protection of human subjects in biomedical and behavioural research. The Belmont Report endorses three core bioethical principles in researches dealing with human subjects, namely respect for human persons / dignity, beneficence and justice. This foundational statement is the driving force for the proper functioning of all Bioethics Committees.

Provision in the Helsinki Declaration of 1964, revised in 1975, for the formation of an "Independent Committee" laid the foundation for the functioning of the present bioethical system of Institutional Review Boards whose primary function is to oversee the steps taken to ensure the protection of human dignity and human rights. Recognizing the fact that the discipline of bioethics has currently undergone marked cultural and social changes the UNESCO brought out a fresh Universal Declaration on Bioethics and Human Rights (UDBHR adopted on 19.10.2005) which recognizes that "ethical issues in medicine and life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole". Therefore, all IRBs, in principle, must function on the basis of bioethical principles of justice, autonomy, beneficence and confidentiality, thus preserving the social stability.

Importance of Bioethics Committees

Bioethics committees concern themselves with the ethical and moral issues raised in the advancement of science and technology in the fields of Life Sciences, Biosciences and Medical Sciences. It is imperative, therefore, to develop a mechanism to address these issues and provide an impetus to governments and policy makers. Such logistic mechanism goes by the umbrella term of Bioethics Committees. These committees function in any institution where research studies are conducted on animals as well as human subjects so as to provide better health care. Providing improved health and enabling the sick to have the access to health care system is the primary aim of the Bioethics Committees. In health care institutions it provides ethical guidance in the area of doctor-patient relationship, protecting human dignity and maintaining confidentiality to patients living with HIV or AIDS. Depending upon the nature and requirement Bioethics Committee has taken various dimensions such as Research Ethics Committee, National Bioethics Advisory Committee, Policy-making Bioethics Committee, Hospital and Health Care Bioethics Committee and Medical –Health professional bioethics Committees.

Bioethics in India

The advent of 21 century has assured in an era of biosciences ethics. Recent developments in new biology and biomedical sciences and their practical application in research involving human and non-human subjects have necessitated the implementation of Institutional Review Boards (IRB). In an Indian context, the discipline of bioethics was introduced for the first time in 1996 by conducting an international bioethics congress at the University of Madras, Chennai.

A national awareness in bioethics was created with the birth of the All India Bioethics Association (AIBA) in 1996-1997. Bioethical maturity of a society deals with the following aspects: (i) how to control the use or misuse of newly acquired biological and medical knowledge and the tools of biotechnologies (ii) to develop a critical frame of mind and (iii) to develop a system of values that prepare us to judge each new biological, molecular and genetic discovery or biotechnology as it evolves as well as to resolve problems with bioethical dilemma and (iv) it insinuates itself into the awesome and broad domains of the life sciences and health sciences (UNESCO, 2005 a).

Therefore, proper governance of IRBs is closely associated with such awareness of core principles of bioethics. Implementation of regulatory bioethical measures through IRBs is to ensure a competent review of all ethical aspects of the research project proposals involving human subjects.

Definition of IRB

A Bioethics Committee otherwise called the Ethics Committee and the Institutional Review Board (IRB) is "a

committee that systematically and continually addresses the ethical dimensions of (a) the health sciences, (b) the life sciences and (c) innovative health policies. A bioethics committee is typically composed of a range of experts, is usually multi disciplinary and its members employ a variety of approaches to work out toward the resolution of bioethical issues and problems, especially moral or bioethical dilemmas. Moreover, the members of these committees not only become more sensitive to ethical dilemmas but also, in time, develop the knowledge and skills required to deal more effectively with them, frequently finding ways to resolve what may at first appear to be intractable dilemmas." (UNESCO, 2005, a).

Bioethics committees generally have no legal authority to prosecute or take legal action against any erring institution. To a larger extent, it protects the Principal Investigator (PI) from any pitfalls in his research which may trigger legal proceedings and it also ensures the protection of human dignity and human rights of the human subjects. Just as it is protecting the investigator against legal proceedings it also safeguards public trust.

World Scenario

IRB - Office for Human Research Protection

In the United States of America (USA) the Office for Human Research Protection (OHRP) maintains a Registry of IRBs of the world (http://www.hhs.gov/ohrp). On a national and international basis, it caters to the interests of human subjects in clinical trials and provides infrastructural support in bioethics by way of strengthening and providing leadership in the national system for protecting volunteers in medical research. It plays a role in capacity building of IRBs in terms of assisting in solving bioethical dilemmas, providing clarification / guidance to research institutions as well as academic inputs in curriculum development in bioethics and for the education of committee members in bioethics. It is recommended that, in every country, similar national organization must be instituted with their own National Registry containing the names of IRBs, ID of website information, if any, information on the area of interest and a list of expert members.

The registry of OHRP provides information on the IRBs of the world, from which information regarding the number of IRBs (that they recognize) in all the countries listed in its registry was culled out to construct the following Tables. Table 1 lists the name of countries with the total number of recognized IRBs, in an ascending order. From this source information Tables 2 and 3 were constructed.

Countries with no OHRP-recognized IRBs include: Albania, Algeria , Andorra, Anguilla, Antarctica, Antigua / Barbuda, Aruba, Bahrain, BassasDindia, Bermuda, Bhutan, Bissau, Bosnia / Herzegovina, Bouvet Island, British IOT, British VISS, Brunei, Brunei Darussalam, Bulgaria, Cape Verde, Cayman Island, Central African Republic, Christmas Island, Clipperton Island, Cocos Keelng Islands, Comoros, Cook Islands, Cyprus, Djibouti, Dominica, Equator Guinea, Europa Island, Falkland Islands, French Guiana, French So/Antarctic lands, Gaza Strip, Gibraltar, Glorioso Islands, Greenland, Grenada, Guadeloupe, Guernsey, Guinea Bissau, Guyana, Heard/Mcdonald Islands, Iraq, Jan Mayen, Jersey, Juan de Nova Island, Kiribati, Kuwait, Libya, Liechtenstein, Macau, Marshall Islands, Martinique, Mauritania, Mayotte, Micronesia, Montserrat, Namibia, Nauru, Netherlands Antilles, New Caledonia, New Guinea, Niger, Niue, Norfolk Island, Oman, Paracel Iss, Pitcairn Islands, Qatar, Reunion, Saint Helena, Saint Kitts/Nevis, Saint Vincent/Grenadines, San Marino, Sao Thom/Principe, Solomon Islands, Somalia, Spratley Islands, Suriname, Svalbard, Swaziland, Togo, Tokelau, Tonga, Tromelin Island, Turkmenistan, Turks/Canicos Island, Tuvalu, Unknown, Vanuatu, Vatican City, Wallis/Futuna, West Bank, Western Sahara, Yugoslavia, Zaire

Countries with one OHRP-recognized IRB include: Afghanistan, Angola, Azerbaijan, Bahamas, Barbados, Belize, Benin, Botswana, Burma- Mayanmar, Burundi, Chad, Cuba, Faroe Islands, Fiji, French Polynesia, Gambia , Guinea, Iceland, Korea Peoples Republic, Laos, Lesotho, Liberia, Luxembourg, Maldives, Mauritius, Monaco, Mongolia, Mozambique, Palau, Panama, Rwanda, Saint Pierre/Miquelon, Seychelles, Sierra Leone, Sudan, Syria, Tajikistan, United Arab Emirates, Uzbekistan, Yeman,

Countries with two OHRP-recognized IRBs include: Madagascar, Congo, Gabon, Honduras, Ivory Coast, Jordan, Kosova, Kyrgyzstan, Lebanon, Macedonia, Mali, Papua New Guinea, Paraguay, Senegal, Slovenia, Tunisia,

Country list of IRBs

It can be inferred from Table 3 that the concept of IRB has not taken roots in almost half the countries of the world. The number of IRBs present in a country may be governed by the degree of advancement in Science and Technology, its per capita income as well as by its land area. For instance, Italy (100) and Australia (106) are countries with less land mass when compared to Canada (175) and Mainland China (159). But they are relatively, thickly populated with IRBs. A critical analysis of the Tables may indicate that more education in Bioethics and in house training in establishing IRBs and its functional features are to be introduced in all these countries where Bioethics Committees have not taken roots or not functioning to solve ethically charged issues – Ethical, Legal, Social Issues (ELSI).

Table 3: Number of countries and the Number of OHRP-recognized IRBs

N. IRBS	N. Countries
Zero	99
One	40
Two	16
Three	13
Four	07
Five	06
Six	06
Seven	02
Eight	05
Nine	08
Ten	04
11-20	16
21-30	08
31-40	05
41-50	03
51- 99	05
100 & Above Hundred	06

Countries with 100 or more IRBs

Table 2 provides data on the number of countries which have one hundred and more IRBs. There are only six countries which fall under this category. It may be noted that India is one among them having a total 137 IRBs. Canada tops the list, followed by Mainland China and United Kingdom,

Table 2: Number of Countries with 100 or more IRBs

Nr.	Country	IRBs
1	Canada	175
2	China Mainland	159
3	United Kingdom	153
4	India	137
5	Australia	106
6	Italy	100

A complete country wise listing was prepared (Table 2). Out of 245 listed countries almost 99 countries do not have a single functioning IRB. About 40 countries have only one IRB. In about 13 countries there are just 3 IRBs. About 16 countries have a few IRBs, i.e. between 11 and 20 (See Tables 1 and 3 for details)

Table 1 Country wise Distribution of ORHP-recognised IRBs: Total Number of countries = 245 (countries with 0,1 or 2 IRBs are listed in text) Source link http://www.hhs.gov/ohrp/

Nr.	Country	Nr. Of IRBs
156	Burkina	3
157	El Salvador	3
158	Haiti	3
159	Latvia	3
160	Lithuania	3
161	Malawi	3
162	Moldova	3
163	Nepal	3
164	Nicaragua	3
165	Saudi Arabia	3
166	Sri Lanka	3
167	Zambia	3
168	Zimbabwe	3
169	Austria	4
170	Bangladesh	4
171	Croatia	4
172	Estonia	4
173	Serbia /Montenegro	4
174	Trinidad/Tobago	4
175	Venezuela	4
176	Cambodia	5
177	Ethiopia	5
178	Iran	5
179	Kazakhstan	5
180	Morocco	5
181	Slovak Republic	5
182	Cameroon	6
183	Ghana	6
184	Greece	6
185	Jamaica	6
186	Norway	6
187	Uruguay	6
189	Belarus (7)	7
190	Kenya	7
191	Armenia	8
192	Bolivia	8
193	Costa Rica	8
194	Dominican Republic	8
195	Malaysia	8
196	Bulgaria	9
197	Guatemala	9
198	Romania	9
199	Ecuador	10
200	Indonesia	10
201	Tanzamia U Republic	10
202	Uganda	10
203	Philippines	11
204	Turkey	12
205	Denmark	13
206	Pakistan	13
207	Portugal	13
208	Singapore	13
209	Georgia	14
210	Ireland	14
211	Egypt	15
212	Switzerland	15
213	Czech Republic	16
214	Netherlands	16
215	New Zealand	17
216	Taiwan	17
217	Vietnam	17
218	Chile	20
219	Finland	21
220	Israel	25
221	France	26
222	Ukraine	26
223	Peru	27
224	Colombia	28
225	South Africa	28
226	Sweden	28
227	Belgium	32
228	Hungary	33
229	Thailand	34
230	Nigeria	38
231	Poland	40
232	Germany	45
233	Mexico	45
234	Argentina	46
235	Spain	52
236	Japan	54
237	Korea Republic of	55
238	Brazil	90
239	Russia	92
240	Italy	100
241	Australia	106
242	India	137
243	United Kingdom	153
244	China Mainland	159
245	Canada	175

A detailed list is provided in Table 1 for countries with more than 2 recognised IRBs. Most countries, which do not have an IRB are the underdeveloped or developing countries. In such countries e.g. Albania, other human rights related problems such as human trafficking of young girls may have to be addressed along side with the establishment of regulatory measures like IRBs. It is likely that a new strategy may have to be followed which will build these countries economically, upgrade their present state of art in of Science and Technology and simultaneously helping them to establish IRBs.

In this context, it may be mentioned that a National Conference "On Alternative IRB Models: Optimizing Human Subjects Protection" was conducted during November 20-21, 2006 at Washington DC, USA. This conference sought to solve emerging future sophisticated bioethical problems. It will be highly contextual if an alternative model to the existing American model of IRB is developed to build these countries from the scratch, both economically and bioethically.

As pointed out earlier, UNESCO advocates the formation of different types of committees to suit different needs and requirements in formulating the ethical guidelines dealing with research on human subjects such as 1. Policy making and Advisory Bioethics Committee 2. Health professional Associations' Bioethics Committee, 3. Health care and Hospital Committee and 4. Research Ethics Committee. But in reality, most hospitals and medical institutions have mostly a single type of IRB to oversee diverse aspects of research projects.

Indian National Scenario: IRB distribution in India

There are about 137 IRBs spread across the nation of India (Table 4). There are 28 States and 7 Union Territories in India. Out of these, only 14 States and 2 Union Territories have IRB. Maharashtra tops the list with 28 IRBs, followed by Tamil Nadu (20), Karnataka (18), Union Territory National Capital Delhi (18) and Andhra Pradesh (10). States like West Bengal, with a big city like Kolkata (Calcutta) has only 6 IRBs (Table 6).

A city wise breakup of figures is given in Table 5. Mumbai stands highest with 19 IRBs followed by New Delhi (18), Bangalore (12), Chennai (12) and Kolkata (06). It is interesting to note that in an ancient and thickly populated city like Kolkata (Calcutta) there are only 6 IRBs. In major cities like Trivandrum, Pune, Jaipur, Mysore, Ahmedabad, Kochi and Goa, the number of IRBs is between five and one. Although there are about 12 IRBs in Chennai, the total number of IRBs for Tamil Nadu State amounts to about 20. Only two cities, Kochi and Trivandrum, in the state of Kerala, have a total of 7 IRBs. In Orissa State there are only five IRBs, all of which are located at the capital city of Bhubaneswar.

Following areas have been mentioned as areas for which IRBs exist, namely biomedical, hospital ethics, scientific/biomedical, bio-psycho-social, biological, bioethical and epidemiological. Most of the Institutions have not mentioned their area of specialization. Such information should be included in the National Registry of IRBs, which is yet to be created.

Table 5: Number of IRBs in different Indian Cities

Location Cities	State	Total IRBs
Mumbai	(Maharashtra)	19
New Delhi,	(Union Territory)	18
Bangalore	(Karnataka)	12
Chennai	(Tamil Nadu)	12
Kolkata	(West Bengal)	06
Trivandrum	(Kerala)	05
Pune	(Maharashtra)	04
Bhubaneswar	(Orissa)	04
Jaipur	(Rajasthan)	03
Mysore	(Karnataka)	03
Ahmedabad	(Maharashtra)	03
Kochi	(Kerala)	02
Goa	(Goa)	01

Table 6: Number of IRBs in Indian States

Nr.	Indian States	Nr of IRBs
1	Maharashtra	28
2	Tamil Nadu	20
3	Karnataka	18
4	New Delhi (UT)	18
5	Andhra Pradesh	10
6	Kerala	07
7	Uttar Pradesh	06
8	West Bengal	06
9	Orissa	05
10	Punjab	05
11	Gujarat	04
12	Rajasthan	04
13	Madhya Pradesh	03
14	Goa	01
15	Mizoram	01
16	Chandigarh (UT)	01

UT = Union Territory

Regional Scenario: YRG CARE - A Case Study

Incidence of AIDS was recorded at Chennai during 1980s by Dr. Sunithi Solomon and her team of research workers. She heads a non governmental organization (NGO) 'The YRG CARE'. This Centre for AIDS Research and Education (CARE) is part of YR Gaitonde (YRG) Medical, Educational and Research Foundation, (YRG CARE). YRG Care as a NGO, works among people living with HIV and AIDS. The IRB of YRG Care, was instituted in 1998 and functions on a local level. i.e. at Chennai and it inducted the President of All India Bioethics Association as one of the IRB members at its very inception.

Its Institutional Review Board (IRB) is a registered body of experts (January 1999). In accordance with the International and National (The Indian Council of Medical Research - ICMR) guidelines on research protocols for conducting research on human subjects, it has a Federal Wide Assurance (FWA) (March 2001) with the Office for Human Research Protections (OHRP)..The tenure of the FWA is renewed after a three-year period.

Composition of Experts

Experts who are IRB members are drawn from diverse fields. They include scientific researchers in biological, social sciences and medical fields. With the primary aim of enforcing protection of the rights and welfare of the human subjects, the IRB has microbiologists, legal advisor, development consultant, social scientists, ophthalmologists, HIV /AIDS activists for women, psychiatrists, economists, bioethicists and general medicine. At one stage there were members who were living with HIV (PLHIV). Its IRB members are dedicated to the health of PLHIV and especially to ensure their easy access to health care. The Board members are required to undergo a course of training/workshop and pass an online test on the prescribed background resource materials. Such academic climate equips IRB members to identify the unethical use, if any, of new developments in biological and medical sciences. The IRB meets usually once in a month, on a Saturday agreed by the members in the previous meeting. The regularity of the meeting is governed by the arrival of new research proposals for review, as well as on going projects. Although the IRB members serve on an honorary/voluntary basis provision has now been made to cover their conveyance expenses to attend the board meetings.

Fixing IRB meetings is meticulously managed by the Coordinator who is specially appointed for this purpose. All Principal Investigators (PIs) are required to submit their proposals well in advance to the IRB Coordinator who finalizes the agenda and distributes the study material to all the IRB members well in advance. One of the difficulties in having continued interest of the IRB members in attending review meetings is that of time. Everybody is too busy during the working days and/or on Saturdays they may be out of city. Yet they find time for this important job. The Coordinator telephones each member, a few days before, and confirms their availability since all are busy. Very rarely a meeting is cancelled due to lack of quorum. Usually meetings are postponed for another Saturday when the members are free and available. All meetings are chaired by the Chairman who is elected by the committee members.

Review Procedure

All PIs, including foreign researchers, are required to present their proposals within the allotted time slot, usually done with power point slides. The IRB scrutinizes the proposal without any fear or favour. Suggestions are made for any improvement with respect to methodology, sample size, and the correctness of the questionnaire to be administered in studies that involve a survey. All PIs of such projects are required to state the objection that was pointed out in the earlier review along with the remedial steps taken to concur with the earlier remarks. All revised proposals are finally submitted for approval. No research project is approved without the collective decision of the IRB members. The IRB coordinator electronically records the proceedings and distributes the minutes of the meeting one week prior to the meeting and maintains all files and

correspondence. All IRB approved projects are submitted to the Central Ethics Committee of ICMR for its review and approval.

Effective functioning of the IRB has ensured that "all research conducted by YRG CARE is in compliance with the highest ethical standards". For fulfilling the primary purpose of the IRB which is to ensure the protection of the rights and welfare of human subjects in research at YRG CARE each proposal is reviewed as to its content and protocols such as the inclusion and exclusion criteria, informed consents and reports.

The IRB mainly concerns itself with the research proposals of YRG Care. The IRB is fully apprised of the plan of research, the aim of research and its impact and possible risks and ensures the principles of informed consent and voluntary participation, privacy and confidentiality. It also takes into consideration the existence of regional and cultural variations in India. It safeguards the rights and welfare of the human subjects who will serve as the candidates for the research work. Due to the tendency of stigmatisation of HIV/AIDS candidates, extreme care is taken to keep the case history of each candidate as confidential reports. Secondly, researchers who use the case sheet of patients (medical records) for obtaining data for publication purposes are extremely careful to keep such data confidentially and maintain the anonymity of the patients. Similarly blood samples of infected patients would not be allowed to be subjected to another research proposal, if there is no clear statement permitting blood samples obtained under one research proposal to be used in another new research proposal. Such multiple uses of blood samples should have been clearly stated in the informed consent form. If not, no permission is granted to swap blood samples.

Informed consent – A Living Document

In accordance with The Belmont Report and the Indian (ICMR) Ethical Principles and Guidelines for the protection of Human Subjects, greatest emphasis is given to informed consent. Informed consent is a difficult preposition in an Indian context. Illiteracy is one such problem. Secondly, the role of family members and of the Head of a village community can not be underestimated! Rarely the patient is involved in signing an 'informed consent form'. Generally it is the family that takes the final decision.

YRG CARE caters to the medical needs of people with HIV/AIDS within a multilingual community – the Tamils, The Telugus and the English speaking South Indians. Hence, all the informed consent documents in English language are translated into regional languages, Tamil and Telugu languages. Each translation is back translated into English to verify the accuracy of translation by a third person. Translation is redone if there are wide deviations from the meaning of the original English document. Therefore IRB considers the process of obtaining informed consent as of crucial importance. Hence, it considers the signed informed consent form not as some mere piece of paper but as a living document which to be preserved and referred to till the end of the research program. IRB of YRG CARE does not permit oral informed consent. Therefore, meticulous care is taken to enforce the principle of informed consent either by electronic means or by oral explanation, if the patient is illiterate. In the latter case, thumb impressions are counter signed by a witness.

Protocol Deviations

Entrusted with the responsibility of not only the initial review of the research-proposal- protocols, prior to the initiation of the projects but it also has a continuing responsibility of regular monitoring for the compliance of the ethics of the approved program still the completion of the project. Further, if there are any deviations from the reviewed protocol procedures that were earlier approved by the IRB then the PI of the project is required to present his/her proposal again with reasons for the deviation. IRB reviews the proposal again and then approves. As part of continuing review, all the PIs are required to update the IRB members of the progress made in their research project from time to time.

Finally, every PI presents a completion-presentation of their project. Such reports are published in reputed journals and a copy of the reprint of the research paper is posted to all IRB members. Such activities are part of the continuing education of the IRB members. Since, not all IRB members are well versed with the terminology used in AIDS research such repetition helps the education of the members.

Community Development

YRG CARE has two ethics committees. The Community Advisory Board (CAB) provides the needed impetus to design research projects ethically, especially those under the HIV Prevention Trials Unit (HPTU), as well as to enhance benefits for and participation of the community. The IRB members and community workers meet together over a meal to get to know the field work.

ICMR – Central Ethics Committee

All IRB approved projects are submitted to ICMR's Central Ethics Committee (CEC) for its review and approval. The seventeen members of the CEC of the ICMR are experts in the fields of medical sciences, pharmacology, law, social science, as well as heads of different religious groups and others. Inclusion of representatives of different religious groups as well as philosophers has always been a problem due to the fact of different ideological stand taken by different groups on a common bioethical problem. The members meet to review and to sanction clearances to proposals referred by the Department of Biotechnology, the mother-to-child transmission studies referred by National AIDS Control Organization (NACO) and Ministry of Health and the preventive AIDS Vaccine trials being conducted jointly by ICMR, NACO and International AIDS Vaccine Initiative (IAVI). It has also the responsibility of providing clearances to all the proposals referred by the 137 local IRBs. Such a load of work on CEC there is always enormous delay in obtaining ICMR's clearance. As a result, research projects that are funded by foreign funding agencies suffer loss of financial support. Due to such inordinate delays in obtaining the final sanction, there is also the possibility to swap (plagiarism) a research project submitted by one IRB by another.

The Unethical Side

Instances of plagiarism have been reported from time to time. The Society of Scientific Values (SSV) serves as a watchdog to spot any unethical practices in science and technology. Recently SSV has brought to light two instances of plagiarism and data swapping. In one instance is related to a "prominent government report" and the other is a research publication of a nationally reputed National Centre for Cell Sciences. (NCCS) (Padma, 2007). The "horns of bioethical dilemma" is that two different committees - The Institutional Enquiry Committee at NCCS and an Independent Committee - came to contradictory conclusions and recommendations. On this very issue of conflict of interest, the SSV demands immediate creation of "an independent ethics body with sufficient legal powers to enforce integrity in Indian Science"

In the United States of America, besides regular IRBs attached to a recognized institution, there are many other commercial IRBs which work mainly as profit making organizations. Such commercial IRBs have been under the scrutiny of Food and Drug Administration (FDA) of USA. And yet "no governmental agency has systematic data on commercial IRBs" (C-IRBs) (Lemmens and Freedman, 2000). The root cause for the emergence of C- IRBs is the insistence by federal funding agencies and the FDA for the approval by an IRB to qualify a PI or an institution to secure funding. Therefore, the following recommendations have been made. "Within the

regulatory setting, procedural conflict-of-interest rules are essential because of the absence of clear substantive rules in research review and the reliance on the fairness and good judgment of Institutional Review Board members. Current guidelines and regulations lack adequate conflict-of-interest rules and provide insufficient details on the substantive rules… However, conflict of interest rules are essential to safeguard public trust." (Lemmens and Freedman, 2000).

In an Indian context, it may be recalled that at one stage, the UGC introduced the guideline that it was necessary for an academic to qualify for the Ph.D. degree. Then many commercial 'Thesis writing shops" sprung up. In order to prevent the reoccurrence of such a phenomena it must be made mandatory for all Indian IRBs to be registered with a Central Government Agency in India which will have systematic data on infrastructural details of a given IRB.

The Divide between Developed and Undeveloped Countries

When bioethics was introduced into India mindset during 1996, it was widely commented that it is a luxury for India. After a decade of activities, it is now felt that it is a necessity for social stability. Similarly, Coleman and Bouesseau (2006) argue that " the structure of the American IRB system is poor fit for African countries". However, fifteen African countries have jointly formed a networking called the Networking for Ethics on Biomedical Research in Africa" (NEERA) to survey the participating countries' existing systems for ethics review of research involving human participants and develop a strategy for strengthening it" (Coleman and Bouesseau, 2006). Two issues are involved. Will the American regulatory system of IRB work in the countries listed in Table 1 which do not have a single IRB? Secondly, existence of some such regulatory system is better than having none! However, there is a need to adopt the American system of IRB with suitable modifications to suit local conditions.

International Collaboration

The ICMR has provided "Guidance for International Collaboration for Research in Biomedical Sciences" which is regulated by the International Health Division (IHD). Research projects in the major area of Science and Technology have an implication in biomedical research and Human Health. Hence, both the Government of India and the ICMR have signed specific bilateral agreement with other countries. Such a general agreement includes areas such as exchange of scientific personals and information, joint execution of scientific projects, procurement of infrastructural equipment and for organizing conferences and seminars. However, applications for carrying out research projects in India with foreign funding in biomedical / health research are to be submitted to ICMR (IHD). All such research proposals have to be approved by the Government of India, Ministry of Health's Screening Committee (HMSC).

It may be noted that the procedures /instructions and the application format vary from country to country. For instance, in any INDO- US collaboration, applications have to be submitted to NIH Grants for their approval as well as the approval of the respective IRB. The NIH application format may be downloaded from the website **http://grants2.nih.gov/grants/funding/phs398/phs398.html .** All NIH approved research proposals are submitted to the Indian counterpart agencies for the approval of their respective IRBs. In the case of research proposals involving human subjects with HIV/AIDS all proposals that are approved by their respective IRBs need the approval of ICMR's Central Ethics Committee and by the Ministry of Health's screening Committee (HMSC) whose secretariat is in the office of ICMR as well by the National AIDS Control Organization.

In this context it may be pointed out that the National Bioethics Advisory Commission of UK considered 'there are legitimate reasons to question the capacity of host countries to support and conduct prior ethics review' of collaborative research. Nuffield Council on Bioethics is of the opinion "strengthening the ethics review capacity of low and middle-income countries is therefore, an important goal of international bioethics and human rights (Coleman and Bouesseau, 2006).

Influence of Philosophers in the Committee

It has been pointed out earlier that Indian IRBs, unlike the American/European counterparts, may not have a philosopher on its board (Azariah, 2005). The influence of having a philosopher on the Board and in other advisory or legislative body or not having one, can be illustrated by two historic instances.

The U.S. House of representatives recognized that a federal crime against a pregnant women claims two victims, passing the Unborn Victims of Violence Act (H.R. 1997), also known as "Laci and Conner's Law," by a vote of 254-163. The bill would recognize as a legal victim any "child in utero" who is injured or killed during the commission of a (http://www.lifesite.net/ldn/2004/feb/04022603.html) federal crime of violence. Two areas need to be addressed. (1) it is good that it recognizes the rights of a "child in utero". 2) The usage of the world child indicates that the unborn fetus is a person. It remains to be seen how such an implication will be taken by an American philosopher, who may not generally recognize a foetus as a person.

The Great Divide

It is interesting to note that, in the Western Civilization, it is rare to find any bioethics committee without a philosopher. In fact most of the bioethical dictums are influenced by philosophical undercurrent. Socio biologists thought that such a domination is not always good and hence "Scientists and humanists should consider together the possibility that the time has come for ethics to be removed temporarily from the hands of the philosophers and bioligicized" (Wilson, 1975). On the contrary, it is interesting to note that in the Indian context, bioethics was introduced to the Indian intelligentsia by biologists. Hence many natural scientists have become expert-bioethicists. Indian philosophers are immersed in the varied shades of Indian philosophy and hence it is very rarely a philosopher is interested in Ethical Legal and Social Issues (ELSI). Biologists can speak philosophy but it is hard for an Indian philosopher to speak bioethics based on biological concepts since they have no exposure to biology in their collegiate education.

The Unbridgeable Divide

As a result, it has been pointed out in an earlier paper that the Ethical Committee which formulated the Indian Ethical Guideline of Human Subjects in Biomedical Research of 2000 didn't have philosophers on its Board. In consonance with the Indian belief system (cultural/scriptural) it made a statement that the fetus is a person (Azariah, 2005). In this context, the recent judgment of an Indian judge is interesting. An Indian state consumer court (MUMBAI, India, March 7, 2007) has delivered an unprecedented ruling in favour of a woman seeking an insurance claim on the death of an unborn child--the court determined that the unborn baby was a living human being entitled to personhood and required the insurance company to pay the claim (Personal email communication with Prof Bing Tang, NY, USA).

Difficulties in implementation

Guidelines advocated by the ICMR have no legal bindings on any research institutions and hospitals in India. As there is no provision for compulsory enforcement of ICMR ethical guidelines, they are to be adhered to by voluntary compliance. Although these guidelines have been released by a national organization like the ICMR it has no regal authority to take any action against those who violate the rules.

Therefore, one of the greatest difficulties is that of implementation and monitoring. The following question was

asked to Dr. Vasantha Muthuswamy of ICMR "Is there a monitoring mechanism to ensure ethical processes such as informed consent, recruitment and compensation are carried out during the clinical trials? She replied "There is no proper mechanism in position at present. It is recommended that Institutional Ethics Committee take up the monitoring role by site visits to ensure compliance. It will take some more time to make these things really happen" (IAVI 2007). Even though there is a law preventing the misuse of organ transplants, especially with reference to kidney transplants, enforcing the law is far too difficult.

If the task of monitoring the enforcement of ICMR guidelines is left with local IRBs it is far more difficult. Recently, about thirteen hospitals were deprived of their licenses to perform kidney transplants due severe malpractice in kidney trade (Kannan, 2007 a, b., Azariah, 2007). Following are the names of hospitals, in the state of Tamil Nadu, involved in kidney racket: 1.Vedanayagam Hospital (Coimbatore), 2 PSG Hospital, (Coimbatore) 3. Kovai Medical Centre, (Coimbatore), 4.G. Kupuswamy Naidu Hospital, (Coimbatore) 5. Kavery Meidcal Centre, (Trichy), 6. Ramakrishna Nursing Home, (Erode) 7. Galaxy Hospital, (Tirunelveli). 8 Devaki Hospital, (Chennia), 9. Chennai Transplant Centre, Madras Medical Mission, (Chennai), 10. ABC Hospitals, (Chennai), 11.Chennai Kaliappa Hospital, (Chennai), 12. Apollo Speciality Hospital, (Madurai) and 13. Meenakshi Medical Mission, (Madurai). Apparently, in all these hospitals of refute there is no IRB or Hospital Ethics Committee!

Enormous Delay in Future Hopes

Although the ICMR guidelines for biomedical research on human subjects were circulated as a consultation paper as early in 1997 it was finalized only in 2000. However, it was only recently it has been given the shape of a Bill. As on date, the Bill awaits that it is passed as a Law by the Indian Parliament (IAVI, 2007). Almost it has taken seven years to reach this stage, during which the ground realities and cultural and social norms change drastically. ICMR hopes that once the Bill becomes a law then it becomes "mandatory for all clinical studies, conducted by both physicians and non-physicians, to follow the guidelines. Currently, there are laws governing research in India. Under the Drugs and Cosmetics Act all trials in the country should follow the ICMR guidelines. Medical Council of India Act amended in 2002 states that all research in India carried out by physicians has to subscribe to the ICMR guidelines. This is an indirect legal support to enforce our guidelines but we need more teeth!" ICMR also hopes that all researchers in biomedical sciences may undergo a course of training in ethics before taking up a research work. The proposal that all postgraduate theses should go through IRB clearance may not be a reality due to time factor.

Ethics Committees and the Future

There is a need to establish ethical guidelines in animal rights where animals are employed in toxicological research. Technological universities and pharmaceutical companies connected with drug and cosmetic research invariably animals are used. There is on appropriate Scientific Ethical Review Committees which looks into this matter.

Development of human resource to solve our common future bioethical issues and concerns, in newer areas of biotechnological research in genetic engineering, IVF, human embryonic stem cells (hESC) research and human egg donation are areas of exploration and exploitation. Hence, these sophisticated newer fields definitely need safeguards and laws to confer human rights to vulnerable humans. Currently, The Indian Council of Medical Research (ICMR) located at New Delhi takes the responsibility of approving all research projects involving human subjects nationwide and to enforce the principle of non violence in biomedical research by assessing the risks and benefits of these new advancements in science and technology.

One Central Bioethics Committee may not be effective to govern newer areas of research involving human subjects. Afore mentioned national (USA) conference "On Alternative IRB Models: Optimizing Human Subjects Protection" foresaw such a problem. The two main objectives of the conference were the following: (i) To optimize and facilitate institutional access to appropriate ethical and scientific expertise for reviewing increasingly sophisticated projects and (ii) To optimize institutional resources to review such projects.

It is recommended to create a National Bioethics Authority or National Bioethics Commission so as to bring regulatory measures in research involving human subjects as well as non-human subjects. More importantly, regulatory mechanisms, which restrict scientific research in grey areas, are to be considered. These are two aspects which need current attention.

Educating the IRB

Successful Bioethics Committees usually begin the process of education slowly, introducing the process of self-education when they first begin to convene as a group. Bioethics is complex and multifaceted discipline, drawing on philosophy and law as well as science and medicine. Most committee members will lack special training and experience in bioethics, and though they typically have significant expertise in other fields, will be willing to devote some time to this multi-disciplinary field.

In the world of Bioethics Committees the horns of bioethical dilemma are ever changing. With the advancement of new scientific discoveries and new biotechnologies, governments all over the globe are introducing new bioethics-related-policies and regulations with new judicial rulings. With the changing culture new worldviews evolve in a society. Professional attitudes to these new ethical legal and social issues change dramatically. Hence, committee members are to be equipped with bioethical infrastructural cementing factors which will enable them to address the new forms of horns of bioethical dilemmas effectively. Since the issues are multidimensional in nature IRB members need to undergo intensive education. UNESCO advocated self education and long-term intensive education in fields like biology, biosciences, biotechnology, medicine and law. It remains to be seen how effective will be the process of intensive self- education in an Indian context!

It may be recalled that bioethics was introduced in India as early as 1996 through the creation of All India Bioethics Association (AIBA) in Chennai. And yet it has not taken roots into Indian academic curricula. As far as the Tamil Nadu medical curriculum is concerned there the subject of Medical Ethics has not yet been introduced (MCI, 2008). Currently bioethics has not been recognized as an academic discipline in medical schools in Tamil Nadu, of which Chennai is the capital. Hence universities have no Departments of Bioethics. And 'Medical Ethics' has not been taught as a major subject in the medical curriculum. Consequently students are not expected to undergo any university terminal examination to obtain their Degree Certificates in Medicine. If Indian IRBs are to have qualified members on its Ethical Review Committees then it is mandatory that medical students and students of other related subjects as well as IRB members should be well educated in the many areas of bioethics so as to be qualified to serve as members of IRBs. Creating human resource in bioethics is a prerequisite for the good and bioethical governance of research involving human subjects through IRBs. Education in intervention bioethics is an area for immediate concern of crucial importance, if Indian IRBs is to function on internationally accepted norms (Azariah, 2006). It is the recommendation of the UNESCO (2005, a, b) that every country has its own IRBs both at the National and Regional levels. However, in comparison with the extent of the land of

India and number of health-care institutions, there are just a few local IRBs catering to the ethical needs of a given area.

Acknowledgements

My thanks are due to Mr. John Eugene Jesudason, Coventry University for providing logistic support and internet facilities for a period of four moths which enabled me to launch and complete this paper.

References

Azariah, J., 2003 The Long History of India Medical System and Current Perspectives in Health Care Bioethics. IN The Annals of Bioethics. Regional Perspectives in Bioethics. Eds. Peppin, J.F. and M.J. Cherry. Swets & Zeitlinger Publishers. USSE The Netherlands. 285-300 (PP 1-380)

Azariah, J., 2005 Some bioethical Issues in Indian Ethical Guidelines in Biomedical Research on Human Subjects. International Joint Bioethics Congress: Inter-Cultural Bioethics: Asia and the West. Asian Bioethics Association and Turkish Bioethics Association Sanilurfa, Turkey. 14-18, Nov, 2005. Abstract Page No.105 106 & Turkiy Klinikleri Journal of Medical Ethics, Law and History. 13: 165–173.

J. Azariah 2006 Bioethics Education as an Intervention Bioethics. UNESCO International Conference on Bioethics Education. July 26-28, Seoul Korea.(In Press).

Azariah, J., 2007 Future: Sustainable Bioethics of policy and governance amidst ethical dilemmas in organ transplantation through human enhancement. Society for Medical Ethics and Law. *Proceedings of the International Congress on Medical Ethics and Medical Law.* Antalya, Turkey. October 17-20, 2007. (In Press)

Coleman, C.H and Bouesseau, M.C., 2006 Strengthening Local Review of Research in Africa: Is the IRB Model Relevant? *Bioethics Forum*. Friday December 22, 2006 1-4.

IAVI 2007 In Conversation: Dr. Vasantha Muthuswamy. International AIDS Vaccine Initiative India Newsletter , *Sankalp 6: 2* April-May 2007. p. 6 www.iavi.org.in

Kannan, Ramya, 2007 a Transplantation licenses withdrawn: Two Chennai hospitals found quietly of forging organ transplantation orders. The Hindu 13.04.07 p. 1

Kannan, Ramya, 2007 b Organ Donation authorization Panel's Decision likely to go online. The Hindu 19.06.07 p. 5

Lemmens, T and Freedman, B., 2000 Ethics Review for Sale? Conflict of Interest and Commercial Research Review Boards. The Milbank Quarterly 78: (4) 547-584

MCI 2008 Medical Ethics in the MBBS Curriculum soon. The Hindu 05.07.08 p. 14

Padma, T.V., 2007 India "needs Independent Ethics Body" Says Watchdog. SciDevNet 27th February 2007. pp 1-2.

UNESCO 2005a Establishing Bioethics Committees: Guide No. 1. UNESCO, The Division of Ethics of Science and Technology, Paris. Pp 71.

UNESCO 2005 b Establishing Bioethics Committees: Guide No. 2. UNESCO, The Division of Ethics of Science and Technology. Paris. Pp 72

UNESCO 2007 Educating Bioethics Committees. Guide No. 3. UNESCO, The Division of Ethics of Science and Technology. Paris Pp 80.

Wilson, O. E. 1975 Sociobiology: The New Synthesis. Belknap Press of Harvard University Press, l975, pp 562.

Contextualizing Bioethics: The UNESCO Declaration on Bioethics and Human Rights and observations about Filipino Bioethics

- Lukas Kaelin, PhD
Institute for Ethics and Law in Medicine
University of Vienna, Austria
Email: lukas.kaelin@univie.ac.at

Abstract

This paper examines the question of the universality of bioethical norms by contrasting the UNESCO Declaration on Bioethics and Human Rights (UDBHR) with aspects of Filipino bioethics. Starting with an exploration of the vagueness of the concept and scope of bioethics, this paper will in turn discuss the UDBHR and distinguish it from key notions in Filipino bioethics. The outlook of Filipino bioethics that I have observed differs significantly from the UDBHR emphasis on the principles autonomy and justice. This discrepancy leads to some reflections on the culturality of bioethics and on the nature of bioethics in the Philippines. Filipino bioethics as a test case shows the embeddedness of bioethical questions in the cultural context as well as the Western biased scope and content of the UDBHR. This conclusion, however, does not rule out a universalistic approach to bioethics, but it asks to reconsider the culturally biased outlook of its presumably universalistic principles.

1. Introduction

The January 2009 issue of *EJAIB* focused on the ultimately philosophical question about the nature of bioethics. This paper will attempt to provide a contribution to this topic connecting as well the issue raised by Karori Mbũgua about the existence of a genuinely African bioethics as well as the relation between normative and descriptive bioethics discussed by Jon Vegar Hugaas in the same volume. However, this paper will focus on the Asian context (specifically the Filipino context) in relation to the hegemonic Western bioethics discourse. This paper attempts to provide a contribution to the ongoing discussion about whether there can be a normative global bioethics without falling into a form of moral imperialism. Filipino bioethics is used as a test case in contrast with the UDBHR in order to examine the extent of the universality of bioethical norms.

The UDBHR (2005) explicitly argues in favor of a global bioethics, thus – after an introduction into the problematic term "bioethics" (2) – I will provide a short recapitulation of this declaration. I will argue that the UDBHR attempts to bind together the different understandings of bioethics, but that it remains Western in its main orientation (3). The problematic of such an understanding of bioethics is explored in the next paragraph, which deals with the problems of implementing such a notion of bioethics in the cultural context of the Philippines (4). This brings me to a more general point, namely the roots of science as such as well as specific scientific disciplines in a social, cultural and historical context (5). A last paragraph will offer some general remarks about bioethics in the Philippines (6).

2. What is Bioethics? A tentative approach

The literal understanding of bioethics does not provide much guidance in grasping the concept of bioethics: Life-ethics. All forms of ethics are dealing with life in one way or another: If we ask for example with Aristotle what the good life is, or if we ask with John Stuart Mill how we can maximize utility, or if we apply Immanuel Kant's Categorical Imperative, we always deal with