

**MINUTES OF THE NATIONAL BIOETHICS COMMITTEE MEETING
ISLAMABAD, DECEMBER 29, 2010 (Final)**

A meeting of the National Bioethics Committee was held on 29th December 2010, at Pakistan Medical Research Council, Islamabad. The Secretary Health, Chaired the meeting. Following Members attended in the Meeting:

1. Dr. Assad Hafeez, Director General Health, Ministry of Health, Government of Pakistan, Pak Secretariat, Block 'C', Islamabad.
2. Prof. Dr. Zulfiqar Ahmed Bhutta, Prof. of Paediatrics & Child Health, The Aga Khan University, Stadium Road, Karachi -74800.
3. Dr. Huma Qureshi, Executive Director, Member/ Secretary NBC, Pakistan Medical Research Council (PMRC) Shahrah-e-Jamhuriat, Sector G-5/2, Islamabad.
4. Maj.Gen. Abdul Khaliq Naveed, Head Department of Biochemistry & Molecular Biology & Advisor in Basic Medical Sciences, Dean Faculty of Medicine, National University of Science & Technology
5. Dr. Farhat Moazam, Professor & Chairperson, Centre of Biomedical Ethics and Culture
Sindh Institute of Urology and transplantation, Karachi.
6. Prof. Dr. Anis Ahmed, Vice-Chancellor, Riphah International University, Sector I-14, Near Hajj Complex, Islamabad
7. Dr. Aasim Ahmad, Associate Professor / Chief Nephrologist, The Kidney Centre
197/9 Rafiqi Shaheed Road, Karachi-75530.
8. Dr. Maqbool H. Jafary, 65/1C Block 6, P.E.C.H.S. Karachi.
9. Dr. Anwar Nasim, Adviser Science, COMSTECH Secretariat, 3-Constitution Avenue, G-5/2, Islamabad.
10. Mr. Shaukat Ali Jawaid, Editor Inchief, Pakistan Journal of Medical Sciences & Pulse International, Room No.522, 5th Floor, Panorama Centre, Building No.2, Raja Ghuzanffar Ali Road, Saddar, Karachi.
11. Dr. Asmatullah, Assistant Professor, Islamic Research Institute, Islamic University, Faisal Masque Campus, Islamabad.
12. Dr. Farid Khan, 68/1 Khyban-e-Mahafiz, Phase 6, DHA, Karachi
13. Dr. Baqi Durrani, Professor of Medicine, Bolan Medical College Quetta.
14. Dr. Muhammad Zaheen, Deputy Director Management MRE, Provincial Health Services Academy, Duranpur, Budhni Road. Peshawar
15. Prof. Rizwana Chaudhry, Nominee, President CPSP
16. Dr. Nadeem Akbar, Nominee PMDC, Islamabad
17. Nominee WHO Representative, World Health Organization, Islamabad.

The following members could not attend the meeting due to their prior commitment or being abroad:

1. Dr Asma Jehangir, President, Supreme Court Bar Association, Islamabad
2. Prof. Muhammad M. Amin, Dean, Shifa College of Medicine, Islamabad.
3. Dr Saeed-ul-Majeed, President, College of Family Medicine, Peshawar
4. Dr. S. Haroon Ahmed, Director, Psycho Social Centre, 11-13 Hilal-e-Ahmer House, Clifton, Karachi.
5. Dr Anwar Aziz, Principal, State School of Nursing, Mirpur, Govt. of Azad Jammu and Kashmir, Mirpur AJK.

The meeting started with recitation of Holy Quran. The Director General Health welcomed the Secretary Health and the Members of the NBC for taking time out from their busy schedules to attend this important meeting. After the introduction of the members, the Chair asked the Member/Secretary NBC to start the proceedings of the meeting.

Agenda Item No. 4: Confirmation of the Minutes of the Meeting held on 22-5-2010

The last meeting of National Bioethics Committee (NBC) was held on 22-5-2010, at PMRC Research Centre, JPMC, Karachi under the Chairmanship of Dr Zulfiqar A Bhutta.

The Minutes of meeting were circulated to all members and no comments were received from any member.

Decision: Minutes of the NBC meeting held on 22-05-2010 were approved.

Agenda Item No. 5: Briefing of the NBC Activities

Dr Huma Qureshi, Member Secretary, NBC, briefed the members on the activities related to national bioethics committee and the progress made so far. Dr Huma also presented the key issues related to further progress of the NBC. The Secretary Health appreciated her presentation and asked the members of NBC to deliberate on the issues highlighted in Dr Huma's presentation.

Dr Farhat Moazam raised the query on a) progress made on the pending issues of the website, newsletter and the survey of medical institutions regarding their IERCs which was to be conducted through the Pakistan Medical and Dental Council. Responding to these queries, Dr Huma informed that a detailed questionnaire developed by the secretariat with feedback from several members, has already been sent to PMDC for circulation to all medical institutions. Dr Nadeem, nominee from PMDC also confirmed that he had sent the questionnaire to all PMDC approved medical colleges, while other research institutions and large hospitals will also be included in the survey. He however, asked the members that NBC members may inform the PMDC if any of their institution has not yet received the questionnaire. He said that PMDC will collect and share information with the secretariat, who shall analyze the data. The analyzed data will be shared with NBC members as soon as feasible. Regarding other queries, Professor Bhutta indicated that they were resource dependent and will be implemented once the secretariat was empowered to hire staff. It was agreed upon by all members that the newsletter will therefore have to wait. As far as improving the website is concerned, it was pointed out that Dr. Anis Ahmed and Mr. Shaukat Ali Jawed had volunteered to work on this free of any cost to NBC and so this can proceed as agreed upon.

The second question raised by Professor Bhutta was regarding the budget for NBC. He was informed that a budget of Rs 1.3 millions was allocated for the NBC to carry out its regular activities like 2-3 NBC meetings, 4-6 REC meetings and 4 IRB training meetings. Extra budget would be required to support the educational component, such as training the medical and research institution staff on the establishment of IERCs, facilitation of the provinces in the establishment of provincial bioethics committees and the website operationalization.

The Secretary Health and the Patron NBC, said that PMRC should workout financial requirement for at least 02 years and submit it to the Secretary Health for support. The Secretary health also asked the members if there would there be any conflict of interest if the resource allocation for NBC is made to PMRC as according to him, resource allocation to PMRC would be easier. All members agreed to this suggestion that a specific one line budget may be allocated to PMRC for NBC activities with the permission to hire contract staff as and when required.

Decision:

1. Secretary Health asked the DG and NBC secretariat to work out budget for the next year, so that funding and hiring could be expedited.
2. In view of the financial constraints, the newsletter will have to wait. As far as improving the website is concerned, it was pointed out that Dr. Anis and Mr. Shaukat Ali Jawed had volunteered to work on this free of any cost to NBC and so this can proceed as agreed upon.

Agenda Item No. 6: Establishment and notification of Provincial Bioethics Committees (PBCs).

Dr Huma Qureshi told the house that, the Federal Secretary has already written letters to the provincial Health secretaries in connection with the establishment of the provincial Bioethics Committees. In response to the clarification sought by Dr Farhat Moazam as to how the generic term "bioethics" in PBC is to be construed, "it was agreed that the Provincial Bioethics Committees would include both research and clinical ethics components." The Patron NBC, Secretary Health said that, before the provinces start implementing the establishment of PBCs it would be appropriate if we include Provincial Director Generals of Health as Members of the NBC. He said he will initiate a note in this regard.

Decision: The Members NBC welcomed and agreed to the suggestion of the Secretary Health for including the Provincial Director Generals of Health as members NBC and a joint meeting of the NBC including the Provincial DGs of Health shall be convened in February 2011. It was also agreed that the Provincial Bioethics Committees would include both research and clinical ethics components.

Agenda item 7: Activation of Medical Ethics Sub-committee of NBC

The committee was informed that since the establishment of NBC, the MEC subcommittee could not be nominated nor their ToRs notified, therefore not much progress has been made on this issue.

Decision: Dr Nadeem, nominee of PMDC informed that all the decisions taken by NBC on medical and research issues shall be owned by PMDC and in this regard a draft has already been sent to the DG (Health) for approval. This will also include the establishment of the medical ethics sub-committee by February 2011. This move by PMDC was greatly appreciated by all members. It was unanimously decided that the physician pharma guidelines once approved by the NBC shall also be sent to PMDC for implementation.

Agenda item 8: Approval of National Stem cell guidelines developed by NBC:

Members were informed by Prof Bhutta that stem cell guidelines were made by NBC's subcommittee almost 2 years back and approved by all members. These were shared by the secretariat with a subcommittee formed by Human Organ Transplant Authority (HOTA) to develop guidelines for stem cell transplant. HOTA has reproduced these guidelines therefore it is suggested that they should specify that these have been adopted from NBC guidelines

Decision: DG will write a letter to the administrator HOTA to make corrections on the HOTA stem cell guidelines and state that these have been adopted from the guidelines developed by NBC.

Agenda item 9: Notification of Physician Pharma guidelines:

Mr Shaukat Jawaid gave a briefing on the development of physician phrama guidelines which were developed by a sub committee of NBC. These were sent to the DG office for circulation, which was never done and instead another guidelines were developed from a committee formed the DG. It was agreed that as the Director General is the chair of NBC, such parallel activities are both unhelpful and demoralizing for committee members."

Action: The guidelines developed by NBC were not seen by few members and the new DG, therefore it was decided to send these again to all members for key comments within one week, barring which the document would stand approved. These guidelines will be circulated to all medical colleges, societies, pharmaceutical bureau, PMA, PMDC and other stake holders through NBC secretariat for information and action.

Agenda item 10: Clinical Trials and Contract Research Organizations (CROs)

The secretariat informed that many drug trials were being approved from the MoH without ethical approval from NBC and many CROs were approaching the MoH and PMRC to be taken as the approved organizations by NBC to conduct clinical trials in Pakistan.

Decision:

There has been a unanimous consensus among all NBC Members that research is important and should be encouraged in Pakistan but the research must be done ethically. Several members expressed concerns at the proliferation of unregulated, for-profit CROs in developing countries such as Pakistan. Therefore, all trials brought by CROs and Pharma industry which are of national importance or are supported by donor organizations will undergo ethical clearance by the NBC (or its provincial counterparts in due course). This is consistent with the notification number 4-87/09-NBC/RDC/6317 dated 17-02-2010 issued by the DG office. The MOH will define registration criteria for CROs and code of conduct for operations in Pakistan.

The meeting ended with a vote of thanks to the Patron and Chair