



Pakistan Medical Research Council

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MINUTES OF THE MEETING OF NATIONAL BIOETHICS COMMITTEE HELD ON JULY 30 2009, AT PMRC HEAD OFFICE, ISLAMABAD.

A meeting of the **National Bioethics Committee (NBC)** was held on July 30, 2009 at PMRC Head Office, Islamabad under the Chairmanship of Dr. Rashid Jooma, Director General Health, Ministry of Health, Government of Pakistan.

The following members attended the meeting:

1. Prof. Dr. Zulfiqar A Bhutta, Aga Khan University, Chairman, Department of Paediatric, Aga Khan University and Chairman Research Ethics Committee of NBC
2. Prof. Mohammed M. Amin, Dean, Shifa College of Medicine, Islamabad
3. Prof. S. Haroon Ahmed, Director, Psycho Social Centre, Karachi
4. Dr. Anwar Nasim, Adviser Science, COMSTECH Secretariat, Islamabad
5. Prof. Anis Ahmad, Vice Chancellor, Riphah International University, Islamabad
6. Mr. Shaukat Ali Jawaid, Chief Editor, Pakistan Journal of Medical Sciences and Pulse International, Karachi
7. Dr. Aasim Ahmad, Associate Professor /Chief Nephrologist, the Kidney Centre, Karachi.
8. Dr. M Suhail Karim Hashmi, Secretary, (nominee) President, Pakistan Medical and Dental Council, Islamabad
9. Brig. Tahir Aziz Ahmed, (nominee), Surgeon General Pakistan Army, Rawalpindi
10. Dr. Farid Khan, Former Managing Director, Novartis Pharma Pakistan, Karachi
11. Dr. Muhammad Zaheen, Department of Health, NWFP, Peshawar
12. Prof. Rizwana Chaudhry (nominee), President, College of Physicians & Surgeons of Pakistan, Karachi
13. Mrs. Nighat Ejaz Durrani, Registrar Pakistan Nursing Council, Islamabad
14. Dr Huma Qureshi, Executive Director, PMRC, Member / Secretary NBC

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

1. Dr. Khalif Bile Mohamud, WHO representative in Pakistan
2. Dr Maqbool H Jafary, Consultant/Physician Cardiologist, Karachi Institute of Heart Diseases, Karachi
3. Dr. Asmatullah, Professor, Islamic Research Institute, Islamic University, Islamabad
4. Prof. Baqi Durrani, Department of Medicine, Bolan Medical College, Quetta
5. Mr. Ali Ahmed Kurd, President, Supreme Court Bar Association, Islamabad
6. Dr. Sharriatullah Siddiqui, President, College of Family Medicine, Karachi

The meeting started with the recitation from the Holy Quran.

Prof. Rashid Jooma, Director General Health and Chairman NBC welcomed all members. After introduction of NBC members, he asked Dr Huma Qureshi, Executive Director, PMRC/ Member Secretary NBC to start the proceeding of the meeting. She briefed the participants about the activities performed so far and the importance of this meeting as it was time to select new NBC members, look for funding resources, work on development of Bioethics Act and selection of priority ethical issues in Pakistan.

The Member/secretary briefed the members according to agenda items as follows:

Agenda Item 1: Confirmation of the Minutes of the Meeting held on 20-4-2007

The last meeting of National Bioethics Committee (NBC) was held on 20-4-07 in the conference room of PMRC Head office, Islamabad. The meeting was chaired by Maj. Gen (R) Masood Anwar, Executive Director, National Institute of Health, Islamabad in the absence Chairperson NBC, Maj. Gen (R) Shahida Malik the then Director General Health, Ministry of Health, Islamabad.

Minutes were circulated to all members and no comments were received from any member. All members confirmed the minutes of the meeting held on 20-04-2007.

Decision: Minutes of the NBC meeting held on 20-4-2007 were approved.

Agenda Item 2: Actions Taken on the Decisions of NBC Meeting held on 20-4-2007

The secretary NBC, Dr. Huma Qureshi informed the group in detail on the actions taken on the decisions of last meeting. The major items that came under discussion included how to make NBC more functional, draft Bioethics Act 2007, guidelines for stem cells research/regulations, priority ethical issues, ethical clearance of research projects and decision on NBC members not attending meetings.

2.1. How to make NBC more functional?

All NBC members showed concern regarding the functionality of NBC as this meeting took place after about more than two years due to non availability of funds. This issue was discussed in detail and members stressed that there should be continuous source of funding for this committee by allocating specific amount in PMRC budget. The secretary NBC informed the members that this year she has allocated Rs 0.6 million for NBC from the regular budget of the PMRC, to let the ball rolling and will try to get more next year. Members appreciated the efforts of PMRC and also suggested to probe other avenues to fund this committee through WHO, UNESCO and other donor agencies.

Members stressed that NBC should continue to work on the establishment of Institutional Review Boards and Provincial Bioethics Committee as agreed upon in previous meetings. This will not only strengthen the Provincial and institutional set up but will also help in addressing the provincial ethical issues and share the workload from NBC. The establishment of Provincial Ethic Committees will be discussed in the next NBC meeting proposed to be held in November 2009.

Members also suggested that a comprehensive PC-I for "Establishment of NBC at PMRC" may be developed, giving all details of core and expended needs, activities, including capacity building national workshops, meetings, research project review compensation and cost estimates for next 5 years.

The Director General Health, the Chairman of NBC registered the concern of NBC members and assured that he will look into the matter in depth and explore possible sources of funding on continuous basis to make this committee a functional entity. He agreed that a PC-I be developed and submitted to Ministry of Health for approval and funding.

Decision: *A Subcommittee has been constituted for the development of PC-I. The composition is as follows:*

1. Dr. Zaheen Chairman
2. Mr. Farid Khan Member
3. Brig. Tahir Aziz Ahmed Member
4. Dr. Aasim Ahmad *to help the committee when required*

TORs: *The Committee will prepare the PC-I in six weeks and submit to PMRC for onward submission to Federal Ministry of Health for approval and funding.*

2.2. Draft Bioethics Act 2007

The NBC "Legislation Drafting Committee" provided the material to Mr. Justice (Retd) Muhammad Qayyum Malik, a NBC member for formulating the draft ACT. The draft ACT submitted to NBC Secretariat was circulated to NBC members for comments. Members were of the opinion that it deals mostly with the aspect of stem cells, embryo and genetic manipulation and does not address the ethical issues of medical services and research.

Members stressed that the contents of the draft ACT must be decided before asking a legal expert (lawyer) to frame the ACT. It was also suggested that already available Bioethics Legislation Act of South African Medical Council and Indian Medical Council may be reviewed and taken guidance for the development of Bioethics Act for Pakistan.

The members suggested that a legal expert may be hired through a formal agreement so the assignment must be completed in time. The name of Mr. Ahsan Rizvi was proposed by the NBC members. Mr Rizvi is a legal expert and also working on ethics and therefore would be more suitable in developing the Bioethics ACT. All members agreed to this suggestion, however, his availability for this assignment will be checked before an official letter is sent to him. Dr Aasim will let the NBC secretariat know about Mr Rizvi's availability.

It was suggested that a Subcommittee may be formed to work on the "Contents of Draft Bioethics ACT" and after that it will be given to legal expert for formulation.

Decisions:

1. *A Sub-Committee with following composition is constituted:*

1. *Prof. Dr. Muhammad M. Amin*
2. *Prof. Dr. Anis Ahmad*
3. *Dr. Aasim Ahmed*

TORs:

1. *The Committee will work on the "Contents of Draft Bioethics ACT" and submit the document within four weeks.*
2. *These Contents will then be given to legal expert hired for the development of Bioethics ACT.*
2. *A formal agreement with legal expert will be made to undertake this assignment with the time limit of three months*
3. *Dr. Aasim Ahmed will inform the NBC for the availability of Dr. Ahsan Rizvi for this task.*

2.3. Priority Ethical Issues in Pakistan

Members were of the opinion that NBC must figure out all unethical practices whether it is carried out in hospitals, clinical laboratories, infertility clinics or in research. There should be specific guidelines for each discipline to follow.

The NBC "Ethical Prioritizing Committee" had identified ten priority ethical areas to address. Members considered and discussed these ethical priorities and were of the opinion that NBC

may take one ethical issue at a time and work on it in depth. Matter of providing undue incentives to physicians by pharma industry came out as one of the most priority ethical issue and it was suggested that there should be a physician-pharma relationship guidelines.

It was suggested that guidelines may be developed after reviewing internationally accredited document on physician-pharma relationship in addition to other documents developed by the PMDC and Pakistan Pharma Association. Dr. Aasim had a module ready to be shared with NBC for the development of comprehensive guidelines on physician-pharma relationship.

The Chairman NBC suggested the formulation of a Sub-Committee for development of these guidelines.

Decision: *A Sub-Committee with following composition is constituted:*

- | | |
|----------------------------|----------|
| 1. Dr. Shaukat Jawaid | Convener |
| 2. Dr. Sohail Karim Hashmi | Member |
| 3. Mr. Farid Khan | Member |
| 4. Dr. Maqbool Jafary | Member |

TORS: *The available documents will be shared among members of the committee and guidelines will be developed within two months.*

Item No.3: Finances for National Bioethics Committee

All members showed concern over the non availability of finances and support staff for the NBC and its Secretariat and for support of Research Ethics Committee. Members stressed that the Chairman NBC, Director General Health, Ministry of Health, Islamabad must use his good offices to locate finances for functioning of this Committee.

As discussed in agenda item No.2, a PC-I will be developed to procure funds from the Ministry of Health which is within the jurisdiction of Secretary Health. All members agreed to this suggestion and constituted a committee for this purpose.

Members also suggested that NBC should have freedom to raise funds from donors, e.g., WHO, UNESCO, ISECSCO and other sources. It was also opined that joint working with Higher Education Commission (HEC), and Ministry of Science and Technology after widening the scope of NBC can bring more funds for its functioning.

Members were also of opinion that as the budget for current year was allocated by PMRC; the same can be allocated for the following years for different activities of NBC. It was also suggested that there should be some funds allocated to give remuneration to reviewers of the projects submitted to REC for ethical clearance and secretarial staff processing the projects at NBC Secretariat at PMRC and at the office of Chairman REC.

Decisions: *Following steps will be taken to make financial resources available for NBC:*

- 1. A PC-I will be developed within six weeks by the Sub-Committee constituted for this purpose and submit to NBC Secretariat (PMRC) for onward submission to Federal Ministry of Health, Islamabad for approval and funding.*
- 2. NBC Secretariat is allowed to approach various donors/organizations e.g., WHO, UNESCO, ISECSCO, etc for generating funds*
- 3. The Chairman NBC will also probe various avenue to locate finances for NBC and will help in the approval of PC-I.*

Item No.4: Selection of NBC Members and Chairman Research Ethics Committee (REC)

4.1. Selection of NBC Members:

The National Bioethics Committee was constituted and Gazette notified in January 2004. As per notification the tenure of NBC membership is for 5 years and renewable for another term on one time basis.

Most NBC members have completed the first term in January 2009 and hence 50% of them need to be replaced.

The NBC Secretariat obtained the nominations in each category of NBC membership by writing to head of the institutions of public and private sector institutions requesting for nomination of suitable person who is involved in research and or having bioethics background. A good number of CVs were received and secretariat made one page summary of each nomination for presentation in this meeting.

Members discussed the replacement of NBC members in detail and it was suggested that if 50% of the members are replaced with new members than the new members may take long to understand the working of NBC and therefore it was unanimously agreed that all members should continue for another term except for the members who are not attending meetings regularly or those who have retired. The members unanimously agreed to this suggestion.

In the category of religious scholar, the nomination of Dr. Zia-ul-Haq was received without CV from the International Islamic University, Islamabad. However, the name of Dr. Tahir Mansoori the Dean Faculty of Sharia and Law, International Islamic University was proposed for this category by many members. Dr. Anis Ahmed volunteered to get the consent and availability of Dr. Tahir Mansoori for membership in a week.

In the category of nurse three nominations were received. Among them the name of Dr. Anwar Aziz was proposed as she was more qualified, experienced and had contributed efficiently in various nursing assignments given to her through Ministry of health.

For the nomination in the category of General Practitioner, the President College of Family Medicine did not send any nomination. Members proposed following nominations from which one person shall be selected in the category of "General Practitioner":

1. The name of Dr. Saeedul Majeed, President College of Family Physician NWFP Peshawar is proposed by Dr. Shaukat Ali Jawaid.

Brig. Tahir Aziz Ahmad, the nominee of Surgeon General informed the members that from the Army side, the Surgeon General identifies and nominates a suitable person considering the requirement of the Committee.

Decisions:

1. *All NBC members who have been attending the meetings and contributing will continue to hold membership for another term of 5 years.*
2. *All members who have not attended the meetings or have not contributed much in the term shall be replaced.*
3. *All members who have retired or passed away shall be replaced.*
4. *The list of replaced members is given below while all other members shall continue for another term*

S.#	Category	Serving	New proposed	Approved
1	Bio scientists	Dr. Qasim Mehdi	Dr.Farhat Moazzam	Dr.Farhat Moazzam
2	Nurse	Ms. Nighat Durrani	Dr. Anwar Aziz	Dr. Anwar Aziz
3	General Practitioner	Dr. Shariatullah	Dr.Saeedul Majeed	Awaited
4.	Human Rights	Dr. Haroon Ahmad	-----	Will continue as his nomination was made on 12-5-2005
5.	Industry	Dr. Farid Khan	-----	Will continue as his nomination was made on 12-5-2005

5. *Surgeon General Pakistan Army will be approached to confirm the nomination of a member for the next term.*

4.2. Selection of Chairman Research Ethics Committee (REC) of NBC:

The tenure of Chairman REC is of 3 years. Dr. Zulfiqar Bhutta was selected as chairman REC and he voluntarily stepped down after completing 3 years. However, all members insisted that NBC is still in its infancy and at this critical time all members should continue for another term as despite of all constraints he and his team has managed to provide ethical clearance to most of the project in time.

Dr. Bhutta brought into the notice of NBC that he is working without any separate secretarial support for REC work or incentives for secretarial staff and reviewers. He suggested NBC may consider giving incentive to secretarial staff and reviewers of the projects as other organizations like HEC and PSF are giving remuneration in this regard.

He accepted the consensus of the members on his continuation as Chairman REC for another term. He suggested that for more efficient working he would like to have the support of two NBC members one in south (Dr.Aasim) and one in north (Prof. Dr. Muhammad M.Amin). Both the members agreed to support him in the ethical clearance of the projects submitted to NBC Secretariat.

Decisions:

1. *Dr. Bhutta will continue as Chairman of Research Ethics Committee for another term.*
2. *Dr. Aasim and Prof. Dr. Muhammad Amin will help Dr. Bhutta in ethical clearance of research projects submitted to NBC.*
3. *Dr.Bhutta, Chairman REC will devise the mechanism of ethical review with NBC Secretariat and two above mentioned members.*
4. *All REC members may be involved for projects review instead of 3-4 members.*
5. *Budget may be allocated for secretarial staff and reviewers involved in the ethical clearance of the projects.*

Item No.5: Ethical Clearance of National and International Research through NBC

Members were of the opinion that only selected research proposals like following should be submitted to NBC for ethical clearance:

1. Any study that involves a drug being imported in the country
2. Any study that involves international collaboration
3. Any study that is funded from external granting agency
4. Any study where patient cohort extends beyond provincial boundaries

It was suggested that Ministry of Health should issue a circular to all Public sector institutions and the funding agencies that all research projects of above mentioned category must be submitted to NBC for ethical clearance. Once ethical clearance is received the project funds may be released.

Local level projects should be handled either by Institutional Research Ethical Committees (IERC) or Provincial Research Ethic Committees (once established). Therefore the establishment of Provincial Ethical Committee was strongly recommended.

Decision:

The office of the Director General Health will issue specific instructions to all public sector institutions and funding agencies for ethical clearance of national and international collaborative research through NBC.

The meeting ended with vote of thanks from Chairman to all members for sparing their valuable time for this meeting.

Prepared by:

Dr. Huma Qureshi
Member/Secretary, NBC /
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Approved by:

Prof. Dr. Rashid Jooma
Chairman, NBC /
Director General Health