



NATIONAL BIOETHICS COMMITTEE

PAKISTAN

Secretariat:

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NATIONAL BIOETHICS COMMITTEE (NBC), PAKISTAN

INTRODUCTION:

The tremendous advances in the field of modern medicine have while on the one hand, brought immense benefits for human kind, on the other increased the potential for harm many folds also. To minimize harm and protect the interest of individuals, guidelines and mechanisms need to be put in place within the Health Systems of countries. The issue of ethics in health research is being given increasing recognition and importance internationally. The International community and donors are now not willing to recognize and fund research, which has not been put up to ethical scrutiny and received ethical clearance.

In Pakistan no system for ethical clearance was in place and as a result researchers from within country seeking international funding and researchers from abroad linking with researchers and institutions, were facing lot of problems in getting the required ethical clearance for their projects. Further, to protect the interests of people of Pakistan from harm and exploitation in the name of research, there was a need that the Health Research System of the country develops standards, procedures and guidelines for the scrutiny of the ethical aspect of all health research being undertaken within the country.

The Ministry of Health constituted a **National Bioethics Committee (NBC)** according to international guidelines formulated for such committees in consultation with a group of professionals who met under the chairmanship of the Director General Health. The committee is truly multidisciplinary and multi-sectoral in compositions with relevant expertise from across many disciplines of medicine, along with well-respected 'non medical' people representing the interests and concerns of the community. There is also a mix of age and gender to ensure equitable representation on the committee. The Committee has been established in accordance with applicable laws and regulations of the country and in accordance with values and principles of the community it serves.

The committee was approved by the Ministry of Health, Government of Pakistan and notified in the Gazette of Pakistan on January 28, 2004 (**Annex-1**).

ROLE OF NBC:

The NBC has major role of an advisory body dealing with all aspects of bioethics in the health sector in the country. The Committee would promote and facilitate ethical health services delivery, health research and health education. It is an umbrella body linked with the ethical review bodies in organizations and institutions like the Pakistan Medical and Dental Council (PMDC), the Medical Training and Teaching Institutions and universities and the recently constituted Good Clinical Practices (GCP) committee of the Ministry of Health's Drug Division.

It is an independent functioning Committee has two sub-committees:

i) Research ethics committee (REC) to address ethics in research.

Function:

- Develop guidelines for establishment and functioning of ERCs in Pakistan
- Facilitate establishment of ERCs at all levels and regions of Pakistan

- Develop a national ERC (part of the NBC with co-opted members if required)
- Review of national research proposals or specific proposals referred to it
- Capacity development

ii) Medical ethics committee (MEC) to address ethics in medical practice and education

Function:

Capacity development in bioethics including promote and facilitate education in bioethics

- Promote and coordinate bioethics in professional sectors of health
- Identify and provide advice on contemporary and relevant issues in bioethics
- Facilitate a national and religious perspective on issues of bioethics
- Approval and notification by Ministry of Health
- Independence in deliberation and advisory role
- Defining operating procedures
- Transparency in all processes
- Representation of the people of Pakistan
- Provision of co-opted members
Public sector: provincial, Sectors: legal, religious
- External collaborations and training links
- Finalize terms of reference after this workshop
- Establish a working group for drafting SOPs
- Finalization of SOPs by NBC
- The NBC must receive appropriate and sustained core-support in its functions, especially in its early formative phase
- Particular emphasis must placed on capacity development in Pakistan
- Among the activities of the NBC, the development of national guidelines for the ethical review of research must be prioritized.

PATRONS:

The Minister Health and Secretary of Health

CHAIRMAN:

Director General Health, Ministry of Health

SECRETARY:

The Secretary will coordinate the meetings. Look after day-to-day business of the committee. Keep Liaison with national research organizations and international ethics committees.

SECRETARIAT:

PMRC is the Secretariat for NBC and responsible for arranging regular meetings of the committee and implementing its decisions and recommendations.

OPERATIONAL COSTS:

PMRC is bearing the cost of the maintenance of the secretariat from within its recurrent budget as no separate funds allocated to PMRC for NBC activities despite of request made in budget 2006-2007;

COMPOSITION OF THE NBC:

The following is the distribution of membership among various categories of stakeholders:

• Representative (PMDC, CPSP, PMRC)	3 (ex-officio)
• Universities/Medical colleges	2
• Bio Scientists	2
• Academics	2
• General Practitioners	1
• Nurses	1
• WHO	1(ex-officio)
• Journalists	1
• Social Scientists	1
• Lawyers	1 (ex-officio)
• Religious Scholars	1
• Industry	1
• Human Rights Commission	1
• Nominee of Health Department (Balochistan & NWFP)	2
• Nominee of Surgeon General/DGMS, Pak Army	1

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The composition along with the names of members of NBC is given in Gazette notification attached in **Annex-1**.

2. TERMS OF REFERENCE (TOR) OF THE NATIONAL BIOETHICS COMMITTEE (NBC):

1. The Committee will prepare and revise national guidelines for undertaking health related research in Pakistan and will recommend to the Ministry of Health legislative proposals for regulating health related research in Pakistan.
2. The Committee will prepare and revise national guidelines in respect of bioethical issues relating to the practice of medicine in Pakistan and suggest the same to PMDC for implementation.
3. The Committee will advise the Government of Pakistan and all other entities seeking its advice, on all matters pertaining to bioethical issues.
4. The Committee shall review proposals submitted to it in respect of health related research proposed to be undertaken in Pakistan.

5. The Committee will advise PMRC and PMDC on matters relating to education and training in bioethical issues and annually report to the Ministry of Health on the progress made in such matters.
6. The Committee shall grant accreditation to such medical ethics committees which meet with the minimum standards prescribed by the Committee for evaluation and supervision of health related research.
7. The Committee shall investigate allegations of scientific misconduct in research referred to it and make recommendations in respect thereof.

3. STANDARD OPERATING PROCEDURES (SOPs) FOR NATIONAL BIOETHICS COMMITTEE (NBC), PAKISTAN

Standard Operating Procedures" (SOPs) have been developed and approved by the Chairman NBC and is approved by the Secretary Health for Gazette notification (**Annex-3**).

4. NATIONAL TRAINING FOR ESTABLISHING INSTITUTIONAL ETHICAL REVIEW COMMITTEE IN PAKISTAN, 28–30 SEPTEMBER 2005

One of the functions of the NBC Secretariat was to help institutions in the establishment of the Institutional Ethical Review (IERC). In this regard, a 3 day national training was held with the assistance of WHO EMRO where 33 participants; 20 from 10 public health and medical institutions and 13 PMRC were trained. The Secretary Health was the Chief Guest in the concluding session of this workshop.

The major aim of the training was that the institutions attending the training workshop will constitute their ERC within 6 month of the training and report to Chair National ERC and WHO EMRO.

During the training participants were made aware of key areas and issues in ethics in health research, highlighted emerging issues, public health research ethics, genomics and population health and clinical trails (including vaccine related projects) and mechanisms for establishing institutional ERCs.

Following training all 10 institutions have formulated their IERCs.

5. Sub-Committees for Specific Task:

Following sub-committees have been constituted in January 2006 for specific tasks:

- **Sub-Committee of NBC on Stem Cells Research** has developed and finalized the guidelines for conducting Stem Cells Research in Pakistan. This has been approved by the Chairperson NBC and Secretary Health.
- **Ethics prioritizing Committee** has prepared ethical priorities not only of medical research but other ethical issues.

- **Legislation drafting Committee** is preparing draft legislation for ethics in medical research (including stem cells research) considering education, research and clinical aspects.

6. Projects Reviewed:

Since notification, the NBC Secretariat i.e., PMRC Head Office, Islamabad has received 14 proposals and got them reviewed for ethical clearance. Out of these 07 projects were approved, 04 rejected and 03 are under review.

7. NBC Meetings/Workshop

1. Workshop on Research Bioethics March 12-13, 2004 at Best Western Hotel, Islamabad.
2. Meeting of National Bioethics Committee held on August 12, 2004 at PMRC Head Office, Islamabad.
3. Meeting for the Organization of a Training Workshop on Research Ethics held on January 19, 2005 at PMRC Head Office, Islamabad.
4. National Training Activity for Establishing Institutional Ethical Review Committees in Pakistan, 28-30 September 2005, Islamabad.
5. Meeting of National Bioethics Committee held on January 17, 2006 held at PMRC Head Office, Islamabad.
6. PMRC Bioethics and Research Methodology Workshop 10-11 April, 2007 at JPMC, Karachi.
7. Meeting of National Bioethics Committee (NBC) on 20-04-2007 at PMRC Head Office, Islamabad.