

Version-1.2 Amendment in replacement process of absent, resigned or retiring members passed in December 28, 2015 Peshawar meeting

National Bioethics Committee (NBC)

NBC is an approved body by the Ministry of Health, Government of Pakistan and it was notified in The Gazette of Pakistan, dated January 28, 2004.

Purpose

NBC is an advisory body dealing with all aspects of bioethics in the health sector in Pakistan. To play this role, the Committee will:

- Promote and facilitate ethics in health services delivery, health research and health education.
- Be linked with Provincial Bioethics Committees (PBCs),e Ethics Review Committees and Health Care Ethics / Clinical Ethics Committees in various organizations / institutions
- Be resource to PMDC, Medical and Dental Colleges / universities, Good Clinical Practice (GCP) Committee, Drug Regulatory Authority Government of Pakistan etc.

NBC has two major sub-committees:

- Healthcare Ethics Committee (HCEC): Will function as an overarching body to assist and guide education and training in clinical ethics at a national institutional level to help meet the needs of the country. *Annexure I (HCEC TORs)*
- Research Ethics Committee (REC): Will review all research projects (medical or social science) projects involving human subjects and be resource for national training and educating in matters of health related research. *Annexure II (NBC-REC TORs)*

Membership:

It will have 20 members and 11 ex-officio (see distribution below)

1. Ex-officio (11)

For continuity it is expected that one/same individual either the ex-officio member or his/her representative should attend the meetings. (A different individual attending different meetings is not desirable).

- a. Patron
- b. Chairperson
- c. PMRC (Secretary & Secretariat)
- d. PM&DC

- e. CPSP
- f. Surgeon General (Army)
- g. WHO Representative
- h. Provincial Director General Health Services
- i. Registrar Nursing Council
- j. President Supreme Court Bar Association
- k. President Association of Family Physician

2. Members

- a. One nominee each from PBCs from all four province and AJ&K (5)
- b. Others (15)

Membership of NBC will be multidisciplinary, multi-sectoral and pluristic in nature. Members will be from both genders and of a wide age range. Those with background / formal training in Bioethics would be preferred, however individuals who are involved in ethics related activities in institutions should be considered also. . It is expected that members would be from teaching institutions, in clinical practice and research, nurses, dentists, pharmacists, social and basic scientists, and family physicians.

NBC members will have to

- Publicize his/her full name, profession, and affiliation in all NBC related documents, website letter head and any other relevant documents or websites.
- Make public all reimbursement for work and expenses, if any, within or related to NBC
- Declare conflict of interest, if any
- Sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters. (all NBC administrative staff should sign a similar confidentiality agreement).

The tenure of membership shall be for **5 years** (initially 50 % will be replaced to have some continuity). If a member does not or cannot attend three consecutive meetings the member shall be replaced. The provision of renewal for another term will be one time.

Election of New Members

Six months prior to completion of terms of members, the NBC Secretariat shall publicize on the NBC website a call for nominations for new members to fill the positions that will fall vacant. NBC will also send letters to various academic institutions asking for nominations. NBC members, regular and ex-officio, will also be requested to nominate up to 3 individuals. The NBC secretariat will then compile and circulate a coalesced list of all those nominated to ex-officio and regular members for their votes. The deadline for submission of votes will be no more than 10 days after the nominees list has been emailed.

Depending on the number of new members to be elected, each NBC member will rank his/her choice from the nominee list with 1 being the top choice. Members will submit their ranked votes to the NBC Secretariat online within the specified deadline. NBC Secretariat will count number of points received by each nominee as follows - nominees ranked as 1 will receive 5 points, ranked as 2 will get 4 points, ranked 3 will get 3, and so on. These points will be added and the highest ranking nominees will be declared elected.

The Secretariat will announce the election results within 2 weeks following the voting deadline. It will be responsible for maintaining strict confidentiality during the entire election process.

The process of replacement of members that have been absent from three consecutive meeting, or those that chose to resign will be the same as for the members that have completed their tenure.

Meetings

- A minimum of three meetings per year
- NBC meeting shall be held alternately in four provinces and AJ&K .The meeting will be chaired by the chairperson or in his/her absence by the chair of HCEC & REC alternately.
- The PMRC will be the NBC's secretariat and will be the organizer of all meetings of NBC
- Information of the meeting will be circulated at least 6 weeks prior to the date of proposed meeting
- Call for agenda items will be made to all NBC members at least 4 weeks prior to the next meeting
- Minutes of the previous meeting will be circulated electronically not later than 3 weeks after the meeting
- Standing agenda items would be reports from the two sub-committees of NBC (HCEC &REC) and all PBCs.

Quorum Requirements

- The minimum number of members required to compose a quorum will be at least 30% of members (excluding ex-officio).

Independent Consultants

NBC may call upon independent consultants as and when needed to provide special expertise in the committee's deliberations. These consultants may be specialists in different aspects of bioethics, religion, law, specific diseases, research methodologies, social sciences, etc. Consultants may also be drawn from representatives of communities, patient groups, or other special interest groups. Duration of their tenure and their job description will be decided by NBC members specifically for each independent consultants based on the need.

Education for NBC Members

NBC members shall have a need for initial and continued education regarding the ethical issues in Health Care delivery, educations and biomedical research. The conditions of appointment should state the provisions available for NBC members to receive introductory training in the work of an NBC as well as ongoing opportunities for enhancing their capacity Health Care & Research Ethics. These conditions should also include the requirements or expectations that apart from the initial introductory training, continuing education of NBC members is also of utmost importance. Ideally these training sessions/workshops should follow NBC meetings.

This education may be linked to co-operative arrangements with other NBCs in the region, as well as other Ethics Committees in the country. Those NBC members who are also REC members should ideally have some formal training in reviewing research proposals. This may include undertaking online course such as the ones offered by US NIH, CITI, WHO or other agencies, or attending workshops, or even undertaking formal Diploma or Masters level degree courses organized in the country by various institutions. A formal qualification in bioethics, although helpful, is not mandatory.

Documentation and Archiving

All documentation and communication of NBC and its two sub-committees (HCEC & REC) should be dated, filed, and archived. A statement is required defining the access and retrieval procedure (including authorized persons) for the various documents, files, and archives.

Documents that should be filed and archived include, but are not limited to,

- a) The TORs, written standard operating procedures of the NBC, and regular (annual) reports;
- b) The curriculum vitae of all NBC members;
- c) A record of all income and expenses of the NBC, including allowances and reimbursements made to the secretariat and NBC members;
- d) The published guidelines for submission established by the NBC;
- e) The agenda of the NBC meetings;

- f) The minutes of the NBC meetings;
- g) Any other correspondence / documents sent to or by NBC

Finances

- PMRC will bear the cost of maintenance of the secretariat from its own budget with the support from Ministry of Health Services, Regulations and Coordination.
- A fee is charged from research proposal submitted for ethical clearance to NBC-REC. PMRC will maintain the accounts. The fee is charged up front i.e. before review and is meant for administrative cost and is in not related to the outcome of the review.
- The NBC should make efforts to secure funds from agencies like WHO EMRO, Government of Pakistan, Welcome Trust etc.