



**National Institutes of Health
Health Research Institute
National Bioethics Committee (NBC)**



Ref: No.4-87/NBC-REC/21/

Date: 2-6-2021

NBC-REC TOR's Version 1.3

Consequent upon the Reorganization of Health Research Institute; the Research Ethics Committee (REC) of NBC Pakistan is mandated to perform the functions according to the NIH Reorganization Act 2021 under section 14 clause 3 (a), (c),(d), (e): including:

Review of all research (medical or social science) involving human subjects and be resource for national training and educating in matters of health related research, including surveys, drug/device trial, the use of fetal material, embryos and tissues from alive or the recently dead done with

- International Funding specifically given for research done anywhere in Pakistan
- Funded or supported by the Government of Pakistan
- Any other research either done all over Pakistan or is a multi-province
- Drug/devices trials for registration shall be reviewed and approved by the NBC-REC before a study is started

Ensure the ethical compliance of medical and health related research to establish national and international standards.

Membership:

The Research Ethics Committee shall comprise of at least 15 Members including a Chairperson as follows:

1. Membership of NBC-R will be multidisciplinary, multi-sectoral and pluristic in nature. Members will be from both genders and of a wide age range.
2. 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.
3. 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.
4. Members will select the Chairperson through voting for a period of 03 years (extendable to another term).

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.



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- 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).
- Work purely on voluntary basis.

Tenure:

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 (in newspaper and electronically) 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 HRI 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 HRI 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.

Meetings

- A minimum of one meeting per month but the frequency will be based on the inflow of the submissions and the Chairperson will decide upon the date and time of the meeting.
- It can be both on line and physical as deemed appropriate.
- Information of the meeting (like studies to be reviewed) will be circulated at least 2 weeks prior to the date of proposed meeting.
- Call for agenda items will be made to all REC members at least 4 days prior to the next meeting
- Minutes of the previous meeting will be circulated electronically not later than 3 days after the meeting



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Quorum Requirements

The minimum number of members required to compose a quorum will be at least 30% of members.

Co-opted Members:

NBC may call upon independent consultants/ coopted members as and when needed to provide special expertise in the committee's deliberations. These may be specialists in different aspects of bioethics, religion, law, specific diseases, research methodologies, social sciences, etc. The contribution will be voluntary as other members and the process of coopting may be consensual.

They 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 in 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.

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-R and 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 quarterly and annually reports;
- b) The curriculum vitae of all NBC members;



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- 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 minutes of the all meetings;
- f) Any other correspondence / documents sent to or by NBC
- g) Communication with other stakeholders like CPSP, HEC, PMDC and DRAP.

Finances

- Health Research Institute-NIH 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.
- HRI 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.

Fee Structure:

- Nationally funded/ non funded submissions Rs 20,000/-
- Foreign Funded/ foreign collaborative submissions Rs 50,000/-
- Amendments (if major decided by Chairperson) Rs 25,000/-

Routine review process

The duration of approval for a study shall be valid to a maximum period of one (1) year after which a re-approval is required. This will be standard for any study submitted irrespective of its duration whether one (1), five (5) or more years. Any change in conditions that could affect the rights/autonomy/welfare of subjects or serious adverse event during a study must be informed for approval to continue the study.

In exceptional circumstance urgent/expedited review may be done by at least two or more members and the chairman for approval or disapproval. Such approvals shall be reported to the next meeting of REC. The response letter to the applicant should mention that the decision is through expedited review. (This would be in special circumstance and not for convince)

Studies that do not require direct human subject participants e.g. chart review, already collected data for routine public health reasons etc, case reports may be exempted for review. But these studies and NBC-R / REC exemption form would have to be submitted to the REC to issue an exemption certificate. Such exemptions shall be reported to the next meeting of REC.



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Timeline for the process:

- REC review will be sent to PI within six to eight weeks after submission.
- In exceptional circumstances expedited review will be done before 08 weeks.
- Once the review by REC is sent to PI, it is expected that the PI must respond within 2-months, if no response from PI is received at the end of two months, a letter will be sent to PI stating 'that if in the next 1-month the PI does not respond the study will be considered to be abandoned by PI' and will be marked as 'Null and Void' in the Submission Record.

Communication:

All the communication with anyone including but not limited to applicant, media, other stakeholders shall be done only through HRI upon the official letterhead.

The technical matters shall be signed by REC Chairperson.
The administrative matters shall be dealt only by HRI.

This issues with approval of chairperson of REC.

Dr. Nighat Murad

*Focal Person (NBC) / Research Director
National Institutes of Health (NIH)
Health Research Institute (HRI)*