



## **National Bioethics Committee (NBC)**

### **INTRODUCTION**

NBC is an approved body by the Ministry of Health, Government of Pakistan and it has been notified in The Gazette of Pakistan, dated January 28, 2004. It has the major role of an advisory body dealing with all aspects of bioethics in the health sector in Pakistan. To play this role, the Committee would:

- Promote and facilitate ethical health services delivery, health research, health education and medical journalism.
- Be an umbrella body linked with the Ethics Review Committee in various organizations/institutions e.g., Pakistan Medical & Dental Council (PMDC), Medical Colleges/Universities, and Good Clinical Practice (GCP) Committee of Ministry of Health etc.

It is an independent functioning committee for defining the operating procedures and transparency of the process related to all the aspects of health delivery system in the country.

### **THE ROLE OF NBC**

NBC is the major, official body to uphold the bioethical principles in all sectors of health-care in the country. The purpose of NBC is to safeguarding the dignity, rights, safety and well-being of subjects who seek assistance to safeguard their health, be their treatment, as the participants in research projects in the country, as teachers and the taught, and publications in the medical field. NBC is expected to take care of the principle of justice in the equitable distribution of resources for health delivery. It is within the right and responsibilities of NBC to critically monitor the actions of any subcommittee formed under its umbrella.

**Secretariat:** Pakistan Medical Research Council, Shahrah-e-Jamhuriat, Sector G-5/2, Islamabad is the Secretariat of NBC and responsible for all the functions of NBC.

# GUIDELINES FOR APPLYING FOR ETHICAL CLEARANCE OF RESEARCH PROJECTS FROM NATIONAL BIOETHICS COMMITTEE

## **SECTION 1: SOPS FOR RESEARCH ETHICS COMMITTEE (REC)**

### **PROCEDURE FOR SUBMITTING AN APPLICATION**

#### **(a) *Application***

An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research.

#### **(b) *Application Requirements***

The requirements for the submission of a research project for ethical review should include the following:

- a) The application should be submitted to Secretary, REC (Executive Director, PMRC).
- b) The application form(s);
- c) The documentation (see 3d);
- d) 2 originals of projects should be submitted.
- e) The receipt of applications will be acknowledged by REC including the communication of the incompleteness of an application including the need for any supplementary information or changes to the document within two weeks of receiving the application.
- f) The notification of the decision following review within three months in case of complete application.

#### **(c) *Fee structure***

##### **a. Internal funded projects:**

##### **Normal review (Within 12 weeks):**

- Individuals (not sponsored): Rs. 2,000/-
- Sponsored studies : Rs. 10,000/-

**Expedited review (Within 6 weeks):**

- Individuals / Institutions: Rs. 5,000/-
- Sponsored studies : Rs. 20,000/-

**b. External Funded projects:**

**Normal review (Within 12 weeks): Rs 20,000**

**Expedited review (Within 6 weeks): Rs 50,000**

**(d) *Documentation***

All documentation required for a thorough and complete review of the ethics of proposed research should be submitted by the applicant.

This may include, but is not limited to:

- a) Signed and dated application form;
- b) The protocol of the proposed research (clearly identified and dated), together with supporting documents and annexures;
- c) A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation ('flowchart') of the protocol;
- d) A description (usually included in the protocol) of the ethical considerations involved in the research;
- e) Case report forms, diary cards, and other questionnaires intended for research participants;
- f) When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of the product's characteristics) should be submitted;
- g) Investigator(s)'s curriculum vitae (updated, signed, and dated);

- h) Material to be used (including advertisements) for the recruitment of potential research participants;
- i) A description of the process used to obtain and document consent;
- j) Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
- k) Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
- l) A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
- m) A description of the arrangements for indemnity, if applicable;
- n) A description of the arrangements for insurance coverage for research participants, if applicable;
- o) A statement of agreement to comply with ethical principles set out in relevant guidelines;
- p) All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other RECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.