GUIDELINES FOR APPLYING FOR ETHICAL CLEARANCE OF RESEARCH PROJECTS FROM NBC:

SECTION 1: SOPS FOR RESEARCH ETHICS COMMITTEE (REC)
PROCEDURE FOR SUBMITTING AN APPLICATION

(1) 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.
(2) 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) 02 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.

(3) Fees Structure

(4) 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.

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