INSTITUTIONAL BIOETHICS COMMITTEE (IBC)
UNIVERSITY OF KARACHI

GUIDELINES FOR RESEARCHERS

GENERAL PRINCIPLES

- All research projects involving human subjects, whether as individuals or communities, including the use of human material, and tissues from the recently dead, supported and undertaken by faculty, staff or students of University of Karachi wherever conducted, shall be reviewed by the IBC before the study begins.

- Some research that involves human subjects may be exempted from the regulations requiring IBC approval. Examples include educational research, testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects financial standing, employability, or reputation. Also exempted are the use of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. All researchers must give the subject participants the option of sharing the results and specify how this will be done.

- Every research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others.

- The human subjects in your project must participate willingly, having adequately informed about the research. If the human subjects in your project are part of a vulnerable population, such as prisoners, children or mentally handicapped then the researcher should clearly state why is it necessary to have such groups as their research subjects and how do they plan to administer the informed consent.

  Essentials of informed consent are:
  - **Purpose** of research
  - **Benefits** of the research to the society and, possibly, to the individual human subject plus person(s) undergoing research.
  - All **foreseeable risks or discomforts** to the subjects. Note this not only includes physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
  - **Length of time** subject is expected to participate.
  - **Person to contact** for answers to questions, or in event of research related injury or emergency.
  - Statement that **participation is voluntary** and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
  - Subjects **right to withdraw** from the study at any time
  - How sharing of results with subjects will occur.
  - No abbreviations will be used.

  Consent document must be clearly written and understandable to subjects (local language as well wherever applicable). The language must be non- technical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical or medical terms must be plainly defined.

- The researcher should also submit to the committee, for review, information regarding funding sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

- The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles of Helsinki Declaration.

- The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

- In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.

APPLICATION

- A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application for review of the ethics of proposed biomedical research.

  The procedure is as follows:

- All information and application forms are available from:

  Office of the Dean, Faculty of Pharmacy & Pharmaceutical Sciences
  University of Karachi
  Karachi
  Pakistan. Tel: (9221) 99261367

- IBC meets thrice a year.
- Applications will be acknowledged and researchers shall be informed of the review date. The researchers shall also be communicated regarding the incompleteness of an application. This will obviously delay the review process.
- The outcome of review shall be communicated to the researchers within a week after the IBC meeting.
- In cases where the IBC requests supplementary information or changes to documents from the applicant, such information should be provided at least a week before the next meeting.
- Researcher may be asked to present the case in the meeting if required.
  - Follow-up (of the researcher)
  - At the end-report

DOCUMENTS FOR SUBMISSION

- Three copies of research protocol (clearly identified and dated), together with supporting documents and annexes. This should always include description of the ethical considerations involved in the research.
- 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).
- A description of the process to be used to obtain and document consent.
- Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required in other languages.
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
- A statement of agreement to comply with ethical principles set out in relevant guidelines.
- All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other IBC 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.

APPROVAL CONDITIONS

- Approval is given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being effected.
- Approval is given on condition that a copy of the research project final report is lodged with the Ethics Committee for its information.

  Approval is given subject to researchers notifying the Ethics Committee if and when a project is curtailed, terminated or completed.

  Approval is given for therapeutic trials subject to the principal investigator notifying the Ethics Committee within seven (7) days (14 in case of unforeseen circumstances) of any adverse event or occurrence that takes place during that trial.

CHECKLIST FOR IBC APPLICATION

This checklist was prepared in order to aid investigation in preparing a complete application and to help expedite review by the IBC. Your cooperation in completing it will be greatly appreciated.

PRINCIPAL INVESTIGATOR'S NAME: _____

DEPARTMENT: _____

☐ Copy of drug brochure or any supplementary information enclosed (if applicable)?

☐ Three copies of informed consent both in English and Urdu or any other local language of the population study.

☐ Three copies of any Questionnaire being administered during the study (if applicable).

☐ Copy of Project

I have made a copy of this entire application for my files.

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Signature: Principal Investigator Date

INSTITUTIONAL BIOETHICS COMMITTEE (IBC)
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INTRODUCTORY QUESTIONNAIRE

Title of protocol: _____

Principal Investigator and Co-Investigators: _____

NAME	DESIGNATION	DEPARTMENT
NAME	DESIGNATION	DEPARTMENT
NAME	DESIGNATION	DEPARTMENT
NAME	DESIGNATION	DEPARTMENT

1. Project involves the use of
   Check all pertinent ones

   a) ☐ Experimental drug(s)
   b) ☐ Radioactive agents
   c) ☐ Non-therapeutic research
   d) ☐ Non-approved use or non-approved dose for approved drugs
   e) ☐ Experimental surgical procedures
   f) ☐ Behavioral research
   g) ☐ Other (please specify):

1. What is the purpose of the study?

2. Enumerate the objectives of the study

3. Description of methods used in protocol.

4. a. Expected duration of the study period

5. Subject information.
   a) Types & number of subjects to be studied (give details of patients and controls)

   b) Age range: _____

   c) Sex: ☐ Male ☐ Female ☐ Both

   d) If subjects are either children, pregnant women, mentally retarded, or prisoners, give brief explanation of need to use these particular individuals.

7. Compensation (to research subject):

Monetary: ☐ No ☐ Yes Amount Rs. _____

Reimbursement of expenses: ☐ No ☐ Yes

_____ Type and amount _____

8. What are the adverse effects expected by the subjects involved in the investigation during the study and what is the provision for managing these effects and who will pay for them?

9. What are potential benefits, if any, to be obtained by participants or society as a result of this study?

10. Location of study:

11. Laboratory studies:

a) Will any tests be performed which are not routinely included as part of the work-up for these types of patients?

b) Who or what agency will pay for these tests?
