ZIAUDDIN UNIVERSITY

ETHICAL REVIEW COMMITTEE

APPLICATION FORM

(Adapted with permission from the Aga Khan University ERC application form)

CHECKLIST

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

PRINCIPAL INVESTIGATOR'S NAME: _____

DESIGNATION: _____

DEPARTMENT: _____

- ☐ One copy of ERC Application form with checklist
- ☐ One copy of research protocol
- ☐ Copy of drug brochure or any supplementary information enclosed (if applicable)?
- ☐ One copy of informed consent both in English and Urdu or any other local
- ☐ language of the population study.
- ☐ One copy of Questionnaire being administered during the study (if applicable).
- ☐ I have made a copy of this entire application for my files.

_____ _____

Signature: Principal Investigator Date

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INTRODUCTORY QUESTIONNAIRE

(Kindly type or print)
Add more sheets for additional space wherever needed

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) Fetal research
- ☐ g) Behavioral research
- ☐ h) Gene molecular cloning
- ☐ i) Other (please specify):

Please provide details in case a or d is checked

2. What is the purpose of the study?

3. Enumerate the objectives of the study

4. Description of methods used in protocol.

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5. a. Expected duration of the study period to be completed.
   b. Expected duration of study on each individual subject. What is the d/f time line?

6. Subject information. Proforma attached for details

a) Group: ☐ ☐ ☐ Other
   Records: Name, age, duration of diseases, complication etc.

b) Age range:

c) Sex: ☐ Male ☐ Female ☐ Both

d) If subjects are children, pregnant women, mentally handicapped, or prisoners, or if it includes foetal research, give brief explanation of need to use these particular individuals.

7. Criteria for inclusion and exclusion patients and controls (type separate).

8. Compensation:

a) To research subject:

Monetary:	☐ Yes	☐ No	Amount: _____
Other:	☐ Yes	☐ No	Specify: _____
Reimbursement of expenses:	☐ Yes	☐ No	Type & amount: _____

b) To Investigators: ☐ Yes ☐ No

If yes, then:

☐ Monetary: ☐ Travel: ☐ Gifts: Amount: _____

Other Specify: _____

9. (a) What are the adverse effects expected to the subjects involved in the investigation during the study and (b) what is the provision for managing these effects? (c) Who will pay for them?

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

11. Location of study:

☐ Outpatients clinics ☐ Inpatient units ☐ ZMU Department:

☐ Other than ZMU (please specify the location) Other hospitals and dental clinics within the boundaries of Karachi metropolis.

12. 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?

13. Discuss ETHICAL ISSUES involved in the study.

14. Any other information relevant to the study in context to Pakistan?

15. Has this study been conducted elsewhere earlier?