UNIVERSITY OF KARACHI

INSTITUTIONAL BIOETHICS COMMITTEE (IBC)

CERTIFICATION

1. Project # :	2. Protocol Version Date: (Required for Amendments) _____/_____/_____ m m d d y y y y
3. Project Title:	
4. Principal Investigator (PI) Department & Complete Address:	
5. Co-Principal Investigator(Co -PI) Department & Complete Address:	
This activity has been reviewed and approved by the IBC in accordance with guidelines provided by Helsinki declaration and guide for the care and use of laboratory animals, National Academy of Science, National Academy Press, Washington, DC.	
6. Approval Type: Original ☐ Amendment ☐ Renewal ☐	
7. Review Type: Full Board ☐ Expedited ☐	
8. Date of IBC Review ____/____/_____ m m d d y y y y	
9. Approval Period: Effective: ____/____/_____ Expiration: ____/____/_____ m m d d y y y y m m d d y y y y	
10. IBC Comments:	
11. IBC Registration Number:	
The Official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed & certification will be provided.	
12. Name of IBC Convener: Prof. Dr. Iqbal Azhar	
13. Title of IBC Signatory:	
14. Signatures:	

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

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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?
