Research Grant Application
King Edward Medical University
Lahore, Pakistan.

For RC use only

Proposal Identification Number

RESEARCH GRANT APPLICATION FORM

COVER SHEET FOR PROPOSAL

TITLE OF PROPOSED PROJECT
RESEARCH DOMAIN ☐ Basic Sciences (please provide clinical relevance in 500 words on a separate sheet) ☐ Clinical Sciences
PROJECT SUMMARY. Describe the proposed research using (about 250) words.
PRINCIPAL INVESTIGATOR / Co-investigator with POSITION & DEPARTMENT 1. 2.
MAILING ADDRESS
Telephone: Email:
CO-PRINCIPAL INVESTIGATOR Name & Position Professional Address

PROPOSED DURATION OF PROJECT: (*in months*)	PROPOSED STARTING DATE	TOTAL FUNDS REQUESTED

SIGNATURE OF PRINCIPAL INVESTIGATOR	SINATURE OF CO-PRINCIPAL INVESTIGATOR
Date	Date

A. PROPOSED GOALS / OBJECTIVES (please identify quantifiable goals)

i. If the proposed research is basic, please identify or postulate scientific hypothesis on which your proposed goal is based.
ii. If the proposed research is clinical, please clearly state the goals and objectives that will benefit public at large.

HYPOTHESIS/BASIS OF RESEARCH (if basic research).

GOALS/OBJECTIVES (please quantify your objectives in case of Clinical research).

1.

2.

3.

4.

B. INTRODUCTION & BACKGROUND OF THE RESEARCH PROBLEMS TO BE ADDRESSED

Please also State Inclusion and exclusion criteria, randomizing and blind controls if applicable.

(PLEASE ATTACH ONE SHEET ONLY)

C. RESEARCH PLAN: SCHEDULE / PHASING

(PLEASE ATTACH ONE SHEET ONLY)

D. SUBJECT WELFARE / SAFETY

If the proposed research project involves human or animal subjects please provide measures taken to ensure their welfare, dignity and safety (please see Appendix I for guidelines).

(PLEASE ATTACH TWO SHEET ONLY)

E. REFERENCES

(PLEASE ATTACH TWO SHEET ONLY)

F. PRINCIPAL INVESTIGATOR / CO-INVESTIGATOR Information

A brief resume of research accomplished in the last 05 years. 1.Please attach C.V. of Principal Investigator 2.Please attach C.V. of Co-Investigator

G. FUNDING REQUEST: ESTIMATED BUDGET FOR THE PROPOSED RESEARCH PERIOD

Honorarium for PI or Co-PI will not be entertained.

DESCRIPTION	Amount (Rs.)
Research Assistant	
Secretarial Help	
Equipment Detail & Justification required	
Disposables Detail & Justification required	
Miscellaneous (Explain) Miscellaneous but vital and extremely essential expenses for running the project include but are not limited to the following items.	
Total	

For further information/assistance please contact office of the undersigned.

Prof. Dr. Faisal Masud

Vice Chancellor
King Edward Medical University, Lahore, Pakistan.

Appendix I

KEMU Ethical Review Committee (ERC)

General Guidelines for Use of Human Subjects

1. All research projects involving human subjects, whether as individuals or communities, including the use of fetal material, embryos and tissues from the recently dead, supported and undertaken by KEMU faculty, staff or students, wherever conducted, shall be reviewed by the Ethical Review Committee (ERC) before the study begins.

2. Some research that involves human subjects may be exempted from the regulations requiring ERC 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. Such exemption would be conditional to:

- The informed consent is taken from the research subject.
- The information gathered being relevant/beneficial to the research subject and his/her community.
- Proposal includes planning for sharing study findings with the research subject/s and the relevant communities planned, as well as mechanisms for informing the research subject.
- Also exempted are the uses of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. Examples:
- Literature review; and theoretical analysis. In such cases the only ethical Concern would be acknowledgement of sources.
- Analysis of data, documents, specimen, not linked to individual subjects.
- Evaluation studies of intervention programmes/projects, especially by those who were partners in planning the intervention.
- All researchers must give the subject participants the option of sharing the results and specify how this will be done.

3. Every medical 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.

4. The human subjects in your project must participate willingly, having been informed about the research. Please provide all information that is likely to affect the person irrespective of age, sex, or literacy level of the subjects. 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:

4.1) Comprehension
Investigator must ensure that the informed consent is clearly comprehended by the subject/guardian.

4.2) Purpose of research must be clearly explained.

4.3) Procedure

In simple word describe the procedure that the subjects would be expected to undergo. Identify any procedures that are experimental/ investigational/ non-therapeutic. Indicate type and frequency of monitoring during and after the study.

4.4) Length of time subject is expected to participate. If subject's participation is expected to continue over a long period of time, please indicate that any new information that develops during the study and may affect the subjects' willingness to continue participation will be communicated to them. This would apply even when the intervention/investigation phase of the study has ended but monitoring continues.

4.5) Benefits of the research must be shared with/communicated to:
- a. Subjects
- b. Other study participants
- c. Society

In studies evaluating drugs or other products the subjects should be advised as to the availability of the product after discontinuation of the study. Please indicate whether drug would be available to the patients free of cost. If not, kindly specify expected local cost.

4.6) Please specify financial burden to be incurred by the research subject while participating in the study.

4.7) Explain 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. If risk is unknown, state so.

4.8) Treatment for adverse experiences Explain what therapeutic measures would be available to the subjects in case of adverse reactions or injury as a result of being a participant in the study. All research related adverse reactions are the financial responsibility of the researchers.

4.9) Confidentiality
Describe the extent to which confidentiality of records identifying the subject will be maintained.

4.10) Person to contact for answers to questions, or in event of research related injury or emergency.

4.11) 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.

4.12) Subjects right to withdraw from the study at any time.

4.13) How sharing of results with subjects will occur.

4.14) No abbreviations will be used.

Consent document must be clearly written and/or verbally explained so as to be understandable to subjects (local language 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. It is PI's responsibility to ensure quality of consent procedure.

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

6. Specify the cost of management directly related to the study and indicate what portion of the cost would be incurred by the study participants.

7. The researcher should also declare any personal and institutional benefits (monitory or otherwise including travel) accrued through study participation.

8. Please also specify benefits of the study to the funding agency or sponsors if any.

9. The research protocol should indicate that there is compliance with the principles of Helsinki Declaration. In case of conflict kindly specify the particular clause, which is being contravened.

10.

a) Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.
b) Non-medical research should be conducted by suitably qualified persons.

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

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

13. Volunteers and patients should be reimbursed for travel and any out of pocket expenses e.g. any wage loss if applicable.

14. Questionnaire (if applicable) intended for research participants should be included.

15. CIOMS (Council for International Organizations of Medical Sciences) guideline "Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependants are entitled to material compensation. The right to compensation may not be waived".

16. Approval is given for a specified period. If the project takes longer than the specified period to complete, a request for an extension of the ethics clearance should be sought.

17. 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.

18. Research could be audited by ERC during the research period to ensure compliance with guidelines.

References:

International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 1993.

Institutional Review Board Guidebook, National Institutes of Health, USA Year 2000.

Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, Geneva 2000.

General Guidelines for Use of Animal Subjects

Kindly consult the following web site for guidelines on use of animal subjects in research.

http://oacu.od.nih.gov/regs/guide/guide.pdf