IRB-3

NUMS
NATIONAL UNIVERSITY OF MEDICAL SCIENCES

INSTITUTIONAL REVIEW BOARD APPLICATION FORM

For Official use:

Date application received:		Protocol No.	
Full Review	Expedited Review	Exempted Review	Renewal or Modifications

1.

Project Title:			
Researchers	Names/Designation	Institutions	Signature
Principal Investigator			
Co-Investigator			
Co-Investigator			
Submission category: (√ Check all that apply)			
Therapeutic drug(s)	Non-approved dose for approved drugs	Diagnostic Research	a) Experimental surgical procedures b) Experimental use of Devices
Molecular/ Genetic studies	Infectious agents	Animal Research	Patient data
Behavioral Research	Community Research	Radioactive agents	Others (please specify):

2.

Project Summary (Please give a brief background of the study in 250 words or less):
Objectives:
Description of research design/methods/protocol (brief detail of any experimental drug/medical device including dosage, side-effects, invasive/non-invasive procedures, if applicable):

3. PROPOSED RESEARCH SUBJECTS:

Subject information.

a. Group: Patients ☐ Healthy Subjects ☐ Others ☐

b. Age range: _____

c. Gender: Male ☐ Female ☐ Both ☐

d. If vulnerable subjects (children, pregnant women, soldiers in service, mentally handicapped individuals, foetus) are involved, give brief explanation to justify the need to use these particular individuals.

e. Inclusion and exclusion criteria of patients and controls (type separately).

f. Expected duration of study period

From:		To:	

4. POTENTIAL RISK TO THE PARTICIPANTS

a. Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

b. What are the provisions/measures for managing these cases?

c. Specify the potential benefits of the study to the participants, if any:

d. Specify the potential benefits of the study to the society at large, if any:

5. FUNDING

Source of Funding: _____

6. SETTINGS /FACILITIES TO BE USED FOR THE STUDY (In case of multi-centered studies, kindly list the name of participating centers/countries):

a. Inpatient_____ b**.** Outpatient_____

Department(s) (Please specify): _____

7. CONFIDENTIALITY AND DATA STORAGE: How will confidentiality of the data collected be maintained?

8. CONSENT FORM OF PROPOSED STUDY AS PER ETHICAL GUIDELINES ATTACHED?

Yes /No

9. DISCLOSURE OF CONFLICT OF INTEREST:

10. DECLARATION BY PRINCIPAL INVESTIGATOR:

As Principal Investigator, I am responsible for the ethical conduct of this study and will adhere to any stipulations of the NUMS-IRB, protect the rights and welfare of research subjects. I agree to conduct the research as presented in this application and as approved by the NUMS-IRB, and am qualified to perform the procedures described herein.

I will submit any proposed changes/modifications for review and approval before these are implemented. I agree to notify the IRB of any adverse events that may occur during the study.

I certify that the information provided in this application is complete and accurate.

Signature of PI: _____

I have reviewed this proposal and agree that it is scientifically and ethically sound. I feel that facilities are adequate for research. I recommend the participation of the concerned personnel of my department in this study.

Signature of Dean/Principal/HoD: _____

11. (FOR IRB OFFICIAL USE ONLY):

NUMS' ethical committee decision:

This request for ethics approval has been:	
a. Approved (no additional ethics form is necessary)	☐
b. Approved with conditions (see below comments)	☐
c. Declined	☐
Comments:	

Signature and Seal of Chairman IRB: _____

Signature and Seal of Director/Dean Research: _____