IRB Ref #		
Date:	_____	**Revision #**
Received:	_____	_____

Shifa International Hospital / Shifa College of Medicine / Shifa College of Nursing

RESEARCH APPLICATION FORM

IRB & Ethics Committee
Sector H-8/4 Islamabad
Pakistan
Email: irbshifa@shifa.com.pk

Office: 051-460-3075
Fax: 051-486-3109

A. Submission Category: (Please check all that apply).

☐ New Protocol: (Study never performed. Include all documents listed in Section B.)
☐ Renewal or Modifications (Please complete Form "B")
(Study has previously been approved by IRB. Include the IRB Approval letter.

Check all that apply:
☐ Informed Consent ☐ Protocol ☐ Data Collection Form ☐ Other Application for
☐ Full Review ☐ Expedite Review ☐ Exempt Review

B. Checklist

☐ Two Copies of Research Proposal Application Form with Checklist
☐ Two Copies of Research Protocol
☐ Two Copies of Data Collection Forms (surveys, questionnaires, telephone scripts, data collection)
☐ Two Copies of Patient Information Sheet and Informed Consent Form English with Urdu Translation

☐ Curriculum Vitae And/ Or Other Relevant Documents Evidencing Qualifications of Investigator(S) And Sub-Investigator(S) and all other study team members

☐ Approval from the Departmental Head

☐ Any additional document that require approval
☐ Copy of this application and study documents filed for personal record

A. COVER PAGE

TITLE OF PROPOSAL

TYPE OF PROJECT

☐ Human
☐ Diagnostic
☐ Laboratory
☐ Chart Review
☐ Therapeutic
☐ Others

PRINCIPLE INVESTIGATOR OTHER STUDY TEAM MEMBERS

Principal Investigator: (Person noted as Principal Investigator in the IRB approval notice.)

Name of PI	Title / Position	Department	Contact No.	Signature

Other Study Team Members

Name & Qualification	Title/Position	Department	Signature

B. ABSTRACT

WHAT IS THE PURPOSE OF THE STUDY? (Please give a brief background of the study)

WHAT ARE THE OBJECTIVES OF THE STUDY?

DESCRIPTION OF METHODS USED IN PROTOCOL

PATIENTS SELECTION CRITERIA (Inclusion& Exclusion Criteria)

DURATION OF THE STUDY

ADVERSE/SERIOUS ADVERSE EFFECTS / POTENTIAL HAZARDS
(Explain how these events would be managed and who will bear the cost?)

POTENTIAL RISK TO THE PARTICIPANTS

POTENTIAL BENEFIT TO THE PARTICIPANTS

C. SOURCE OF FUNDING

☐ Funds Required (Complete Budget Form C)

☐ Sponsored

Please specify the name of the funding source: _____

D. SERVICES

Will services at SIH & SCM be utilized which are <u>not</u> considered part of routine medical care?

<u>Payment of Arrangements</u>: If "Yes" is checked in the above section, an explanation of payment arrangements is required and must be included with this submission packet

E. SETTINGS/FACILITIES TO BE USED FOR THE STUDY (In case of multi-centered studies, kindly list the name of participating centers/countries) (Please check all that apply)

☐ Inpatient ☐ Outpatient
☐ Shifa Department (Please specify) _____

F. EXPLAIN WHAT MEASURES WILL BE TAKEN TO SAFEGUARD PATIENT'S/SUBJECT'S CONFIDENTIALIT

G. SECTION APPROVAL

1. Title of Proposal:

_____

_____

_____

2. Principal Investigator:

_____

Location(s) where the study will be performed:

_____

_____

_____

_____

Approval:

I have reviewed this proposal and agree that it is scientifically and medically sound. I feel that beds and other facilities (if applicable) are adequate. I approve the participation of the concerned personnel of my department in this study.

_____ _____

Chairman/Section Head Chairman/Section Head

If workload is required in excess of usual clinical procedures, name the most involved department in the process of the study.

Approved: _____

Chairman, Department of _____

H. OTHER STUDY RELATED INFORMATION

***** The Ethics Committee must approve Informed Consent Form.***
***** Add pages if necessary.***