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

Shifa International Hospital / Shifa Tameer-e-Millat University/Shifa Clinical Research Center

RESEARCH APPLICATION FORM

Institutional Review Board & Ethics Committee (IRB & EC) Office: 051-846-3075
Sector H-8/4 Islamabad Pakistan Fax: 051-486-3109
Email: irbshifa@shifa.com.pk

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.

Application for

- ☐ Full Review
- ☐ Expedite Review
- ☐ Exempt Review

Checklist

- ☐ Research Proposal Application Form with Checklist
- ☐ Protocol
- ☐ Data Collection Forms (surveys, questionnaires, Performa's, data collection etc.)
- ☐ Patient Information Sheet and Informed Consent Form English with Urdu Translation
- ☐ Only one page of resume and Google Scholar of Principal Investigator(s), and Co-Investigator (s)
- ☐ Full financial and conflict of interest disclosure will be provided
- ☐ GCP training certificate is mandatory for Randomized control trial[1]
- ☐ SCRC has reviewed the protocol
- ☐ Approval from the Departmental Head
- ☐ The study team members are identified and authorship agreed as per ICMJE guidelines[2]
- ☐ Surveillance for clinical trial will routinely be provided to IRB/ DSMB (as per definitions of Specific events described in DSMB Protocol)
- ☐ An interim progress and final report will be provided to IRB/ DSMB
- ☐ Signed "Undertaking on Plagiarism" by all the investigators
- ☐ Raw data and Consent forms will be retained (5 years) and submitted upon request if required
- ☐ Any additional document that requires approval
- ☐ Sign Declaration for collaborative study
- ☐ Meet indemnity insurance.

[1] https://gcp.nidatraining.org/overview
[2] http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

A. COVER PAGE

TITLE OF PROPOSAL

_____

_____

TYPE OF PROJECT

☐	Human	☐	Chart Review
☐	Diagnostic	☐	Therapeutic
☐	Laboratory	☐	Animal Study
☐	Device/Innovation	☐	Others

Entity:

☐	SIH	☐	SCM	☐	SCN
☐	SCPS	☐	DRS	☐	SCMT

PRINCIPLE INVESTIGATOR OTHER STUDY TEAM MEMBERS

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

Name of PI + Qualification	**Title / Position**	**Department**	**Signature**
Contact No.		**Email**	

Other Study Team Members:
Before signing the authorship agreement please read the guidelines (Annexure-I)

- Authorship will be based on ICMJE recommendations and guidelines
- All conflicts of interest, real and perceived, and funding sources have been reported at the time of proposal submission to IRB & EC
- All the authors are agreed to be accountable for all aspects of the work

Name	**Title/Position**	**Department**	**Authorship/Contribution Agreement***	**Signature**

*I confirm that I am an author on the above mentioned study, which is currently being submitted for the approval of IRB & EC. By signing this authorship agreement and contribution, I confirm that I agree to all the recommendations/guidelines and terms of aforementioned for the authorship contribution by ICMJE.

B. STUDY DETAILS AS PER ATTACHED GUIDELINE (Annexure-I), Follow below items 1-15 ; For CPSP Synopsis (Use CPSP format as per Annexure-I)

1- WHAT IS THE PURPOSE OF THE STUDY? (Please give a brief background of the study)
Required component:

- Adequate literature review and identification of "gaps" (i.e. what is not known)
- Hypothesis well defined

2- WHAT ARE THE OBJECTIVES OF THE STUDY?
Required component:

- Clear Primary research question
- Clear secondary question (if any)

3- STUDY DESIGN:
Required component:

- Appropriate research strategy
- Appropriate variables selected & defined
- State study design
    - Systematic Review, RCT, Retrospective , Survey etc
    - Observational study, Design Cohort, Case control, Cross Sectional Survey,
    - Qualitative study & survey / Forum groups

4- DESCRIPTION OF METHODS USED IN PROTOCOL
Required component:

- Valid and reliable data collection method
- Inclusion & Exclusion Criteria
- Sample Size determination
- Appropriate choice of controls (if applicable)
- State of subjects randomization or not

5- PATIENTS SELECTION CRITERIA (Inclusion& Exclusion Criteria)
Required component:

- Appropriate sampling method
- Sample size determination
- Appropriate choice of controls (if applicable)
- State if subjects randomized or not

6- STATISTICAL METHODS:
Required component:

- Appropriate method
- Do the statistical test answer the research question
- Valid and reliable data collection method

7- DURATION OF THE STUDY
Required component:

- Mention the duration of the study after approved from IRB

8- ADVERSE/SERIOUS ADVERSE EFFECTS / POTENTIAL HAZARDS

Required component:

- Explain how these events would be managed?
- Who will bear the cost?

9- POTENTIAL RISK TO THE PARTICIPANTS

10- POTENTIAL BENEFIT TO THE PARTICIPANTS

11- EFFORTS AT MINIMIZING SELECTION BIAS, AWARENESS BIAS, DETECTION BIAS:

12- EFFORTS TO LIMIT LOST TO FOLLOW-UP & ATTRITION

13- EFFORTS TO INTEGRATE AND CONTROL FOR CONFOUNDING FACTORS:

14- WORK PLAN / TIMELINE:

Required Elements:

- Appropriate well declared work plan
- Appropriate and adequate follow-up time

15- EXPLAIN WHAT MEASURES WILL BE TAKEN TO SAFEGUARD PATIENT'S/SUBJECT'S CONFIDENTIALITY & DATA SECURITY

16- REFERENCES

Required component:

- Mention at least 6 references from literature

C. SOURCE OF FUNDING

☐ Funds Required ☐ Sponsored ☐ No funding required

Please specify the name of the funding source: _____

D. SERVICES

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

☐ Yes ☐ No

Payment of Arrangements: If "Yes" is checked in the above section, an explanation of payment arrangements is required and must be included with this submission packet. (Use Form C' Budget Form)

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. FULL FINANCIAL DISCLOSURE:

G. SECTION APPROVAL:

1. **Title of Proposal:**

_____

_____

2. **Principal Investigator:**

_____

3. **Location(s) where the study will be performed:**

_____

4. **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.

_____
Chief of Department / Section Head

For any violations from original protocol including methods, study title, sample size, study design, financial disclosure, and consent and authorship agreement is liable for disciplinary action as per IRB &EC rules.

H. OTHER STUDY RELATED INFORMATION

- Add any other information that you deem necessary

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

Declaration for collaborative studies

I _____ certify that I am the Principal Investigator

(Corresponding author) of the research protocol titled:

_____

_____.

And, I will abide by all the rules and regulations of IRB & EC including

For collaborative studies with other institutions

- ☐ Shifa co-investigator identified who will have the primary responsibility of keeping integrity of all data from SIH/STMU and its affiliated institutions and departments
    - Shifa co-investigator:_____
- ☐ PI will present the protocol in IRB meeting as per agenda
- ☐ Supervisor will attend the IRB meeting for Investigators' synopsis/dissertation/thesis
    - Supervisor:_____
- ☐ Due credit will be given to the Shifa faculty, STMU and institution as per authorship agreement. Shifa Co-investigator who has given permission/approval to collect data from the department must be given authorship (First/Second/Third author).
- ☐ Authorship will be based on ICMJE guidelines/recommendations
- ☐ Memorandum of Understanding (MOU) must be in place between STMU/concerned department and outside institution.
- ☐ ***For any violations from original protocol including methods, study title, sample size, study design, financial disclosure, and consent and authorship agreement is liable for disciplinary action as per IRB &EC rules.***

Signature of PI:_____
Contact number:_____
Shifa co-investigator Signature:_____