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

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

## RESEARCH APPLICATION FORM

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| **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 trial1
* SCRC has reviewed the protocol
* Approval from the Departmental Head
* The study team members are identified and authorship agreed as per ICMJE guidelines2
* 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>

## COVER PAGE

**TITLE OF PROPOSAL**

## TYPE OF PROJECT

Human Diagnostic Laboratory Device/Innovation

Chart Review Therapeutic Animal Study 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

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| --- | --- | --- | --- | --- |
| **Name** | **Title/Position** | **Department** | **Authorship/Contribution Agreement\*** | **Signature** |
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\*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.

## 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

## WHAT ARE THE OBJECTIVES OF THE STUDY?

**Required component:**

* + Clear Primary research question
	+ Clear secondary question (if any)

## 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

## 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

## 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

## STATISTICAL METHODS:

**Required component:**

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

## DURATION OF THE STUDY

**Required component:**

* + Mention the duration of the study after approved from IRB

## ADVERSE/SERIOUS ADVERSE EFFECTS / POTENTIAL HAZARDS

**Required component:**

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

## POTENTIAL RISK TO THE PARTICIPANTS

1. **POTENTIAL BENEFIT TO THE PARTICIPANTS**

## EFFORTS AT MINIMIZING SELECTION BIAS, AWARENESS BIAS, DETECTION BIAS:

1. **EFFORTS TO LIMIT LOST TO FOLLOW-UP & ATTRITION**

## EFFORTS TO INTEGRATE AND CONTROL FOR CONFOUNDING FACTORS:

1. **WORK PLAN / TIMELINE:**

## Required Elements:

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

## EXPLAIN WHAT MEASURES WILL BE TAKEN TO SAFEGUARD PATIENT’S/SUBJECT’S CONFIDENTIALITY & DATA SECURITY

1. **REFERENCES**

## Required component:

* + Mention at least 6 references from literature

## SOURCE OF FUNDING

Funds Required

Sponsored

No funding required

Please specify the name of the funding source:

## 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)

1. **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)

## FULL FINANCIAL DISCLOSURE:

1. **SECTION APPROVAL:**

## Title of Proposal:

* 1. **Principal Investigator:**

## Location(s) where the study will be performed:

* 1. **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.

## 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: