

Rashid Latif Medical College, Lahore



**Rashid Latif
Medical College**



**RASHID LATIF
RESEARCH CELL**

Registration No: IRB_____

Received By: _____ Date: _____

RESEARCH PROPOSAL CLINICAL PROFORMA

Title:

Researcher Name:

Supervisor

Signatures and Stamp

HOD

Signatures and Stamp

Ph. No. : _____ **Email ID:** _____

Submit your Research proposals 3 hard copies as well as at irbrlmc@rlmc.edu.pk

Rashid Latif Medical College, Lahore

Title of the Study: An Experimental Study to Evaluate the Effectiveness and Safety of [Intervention] in Patients with [Disease/Condition]

Principal Investigator: [Name, Qualification, Affiliation]

Co-Investigators: [List of Co-Investigators with Affiliations]

Study Site: [Institution Name and Address]

Background and Rationale: [Provide a brief summary of the disease/condition, current treatment options, and justification for the study. Mention the gap in knowledge that this study aims to fill.]

Objectives:

- Primary Objective: To assess the effectiveness of [Intervention] in improving [Primary Outcome].
- Secondary Objectives: To evaluate the safety, tolerability, and secondary effectiveness outcomes of [Intervention].

Study Design:

- Type of Study: Experimental study (Randomized Controlled Trial or Quasi-Experimental Design)
- Duration: [Total Duration]
- Sample Size: [Number of Participants]
- Randomization (if applicable): [Method of Randomization]
- Blinding (if applicable): [Describe Blinding Method]
- Control Group: [Placebo, Standard of Care, or Comparison Group]

- Matching/Adjustment Methods (if quasi-experimental):
[Propensity score matching, statistical adjustments, etc.]

Eligibility Criteria:

- Inclusion Criteria:
 - Age range: [Specify]
 - Diagnosis of [Condition] as per [Criteria]
 - [Other relevant inclusion criteria]
- Exclusion Criteria:
 - Contraindications to [Intervention]
 - Pregnancy or lactation
 - [Other relevant exclusion criteria]

Intervention:

- Experimental Group: [Intervention details including dosage, frequency, or methodology]
- Control Group: [Standard of care, placebo, historical control, or another comparative intervention]

Outcome Measures:

- Primary Outcome: [Define the main effectiveness measure]
- Secondary Outcomes: [Define secondary effectiveness and safety measures]

Study Procedures:

- Screening and Enrollment (if applicable)
- Baseline Assessments
- Intervention Implementation
- Follow-up Assessments

- Adverse Event Monitoring
- End-of-Study Assessments

Data Collection and Analysis:

- Data Collection Methods: [Electronic Data Capture, Paper Forms, etc.]
- Statistical Analysis Plan: [Describe statistical methods, adjustments for confounders, and significance levels]

Ethical Considerations:

- Informed Consent Process
- Confidentiality and Data Protection
- Risk-Benefit Assessment

Safety Monitoring and Adverse Event Reporting: [Describe how adverse events will be monitored, reported, and managed]

Regulatory and Compliance Considerations:

- IRB Approval
- Compliance with Ethical Guidelines for Experimental Research
- Clinical Trial Registration (if applicable)

Budget and Funding Source: [Provide details on funding sources, if applicable]

References: [List key references supporting the study]

Sanctity of data – Affidavit

I, Mr/Ms _____ S/o, D/o _____

Student of _____

working in _____

Under Supervision of: _____

Hereby undertake to abide by the following rules

1. That the data collected during my attachment at RLMC, RLKU, Lahore for which authorization is being granted by the “Institutional Review Board/ Research Committee” for which I have submitted my synopsis titled _____ shall be used exclusively for the purpose of “not for profit” research and will not use for any other purpose what so ever. Any financial gain or patent originating from this research shall be equally shared with RLMC, RLKU, Lahore.
2. The data collected shall be strictly limited to the parameters defined in my synopsis titled _____
3. That the identity of study subjects shall not be revealed.
4. That prior approval for research project (synopsis) has been obtained from the “institutional Review Board/ Research Committee”.
5. That appropriate recognition of institute/ institutes and acknowledgement shall be given to RLMC, RLKU, Lahore in the publication of the paper/papers or any other medium of communication. If it utilizes the data/ graphs/tables/pictures collected from the aforementioned research, furthermore, in any subsequent publication or any other medium of communication and if it utilizes the above-mentioned data/graphs/tables/pictures with proper acknowledgement (as mentioned below). Prior intimation and authorization by “Ethical Review/ Research Committee” should be attached.
6. The aforementioned acknowledgement/recognition shall be mutually decided between the principal investigator (myself) and the in charge of the unit concerned at RLMC, RLKU, Lahore, as per rules framed under intimation to the “Ethical Review/ Research Committee”.

I have read all the clauses of the above written agreement and hereby agree to be legally bound to this agreement in letter and spirit. I also understand that if I am in breach of this contract; I shall lose the right to the data/publication/graphs/tables collected/published (stored in any form physical/electronic) thereof. In addition, RLMC, RLKU, Lahore will reserve the right to initiate proceedings against me at any/all for a deemed appropriate. Research Supervisor (as shown below) shall stand witness and guarantor of this agreement and would be equally liable in case of breach of agreement.

Signature (Principal Investigator)
College I.D. _____

Signature of Supervisor
College I.D. _____

Name: _____ Signature: _____