PAKISTAN KIDNEY AND LIVER INSTITUTE AND RESEARCH CENTER

RESEARCH PROPOSAL SUBMISSION FORM

Please complete this form and submit to:
mailto:PKLI.IRB@pkli.org.pk

FOR OFFICIAL USE ONLY.

Date of Receipt:	Proposal Number:

Please complete this form for all clinical audit/ service evaluations, which are proposed to take place within Pakistan Kidney & Liver Institute and Research Center.
Please note that your Audit / Service Evaluation cannot commence without registering with IRB:

- All documentation to be used in the study must be attached to this form i.e. data collection tool, patient consent letters and information leaflets etc.
- After completion of your project, you will be requested to complete a project report detailing the main findings and recommendations proposed as a result of your audit work. You (as project lead) must report back to PKLI-IRB and ensure actions and lessons learnt are disseminated appropriately.
- You need to comply at all times with the PKLI&RC Policy for Conducting Clinical Audit Projects.
- The information provided on this proposal form will be stored on an electronic database and used for clinical audit purposes, including Annual Reports. All areas of form must be completed before it will be considered.
- Kindly write "Not Applicable" in sections not relevant to your study.

HOW DO YOU CLASSIFY YOUR PROJECT

☐ **AUDIT** ☐ **RESEARCH**

* If you are comparing your practice with the known National or International best practice – it is an audit / Project

IF YOUR PROJECT IS AN AUDIT, PLEASE FILL THE FOLLOWING SHORT QUESTIONAIRE

AUDIT

1. Title:
2. Is this a re-audit?
   ☐ Yes ☐ No

If yes, what was the title of the original audit and the date it was undertaken?

3. Rationale (Background and QI objectives)

4. Standards (The explicit measures of the aspect of care against which practice is being compared. These should be from evidence-based practice or developed based on local knowledge)

5. Do you need any help for data gathering / pulling notes
Yes ☐ No ☐

6.Do you need help with statistics
Yes ☐ No ☐

7. Are there any ethical issues? (Consider patient / staff identifiers and storage / data protection)
Yes ☐ No ☐

If yes, please state.

_____

_____

Audit Lead Name: _____

Designation: _____

Directorate Audit Taking Place: _____

E-mail address: _____

Telephone: _____

HOD/ Chairman
I agree with the aims & objectives of this project and will fully support the action plan and resource the project led to undertaking this work as part of their objectives.

Signed:_____ Print Name:_____ Date: _____

Review Category	**Exempted from Further Review**	☐	**Expedited Review**	☐	**Full Review**	☐

RESEARCH PROPOSAL SUBMISSION FORM

IF YOUR PROJECT IS A RESEARCH STUDY, PLEASE FILL THE FOLLOWING QUESTIONAIRE

RESEARCH PROPOSAL

1. Title of Proposal:

RESEARCH PROPOSAL

1. Title of Proposal:

1. **Type of Research Project:(**Please check all applicable options)

Study Type	Basic Sciences		Clinical Research/ Interventional/ Experimental	
Sub Type	Health Services/ Health Systems/ Health Administration		Therapeutic	
	Public Health/ Preventive Medicine/ Behavioral Science		Laboratory	
	Medical Devices (incl Robotics)		Stem Cells	
	Diagnostic (incl Radioactive Agents)		Pharmaceutical (incl Experimental Drugs)	
	Surgical (incl Experimental Procedures)		Clinical Trial	
Population	Humans		Pediatrics	
	Comatose/Intubated		Pregnant	
	Animals		Other Vulnerable (Please specify)	
Conducting for	MPH/MSc Project		MD/MS Project	
	FCPS Project		PhD Project	
	Other (Please specify)			

3. Proposed Starting Date:

4. Duration of Research Project

5. Principal Investigator (PI):

Name: Mobile No.:

Title/Position: Email:

Affiliation & Address:

6. Name of Co-Investigators: (There is no limit to the number of co-investigators and their expertise should cover the different research areas)

Co-Investigator Name	Contribution	Title/Position	Department/Affiliation	Mobile No

7. Principal Investigator's Assurance:

The undersigned agrees to accept responsibility for the scientific and technical conduct of the proposed research and submission of progress reports if this application is approved. The undersigned also confirms that all the co-investigators have approved the submission of this application.

Name of PI **Signature** **Date**

PRINCIPAL INVESTIGATOR'S DEPARTMENT APPROVAL

Name of Head/Chairperson **Signature** **Date**

8. Aims and Objectives of the Study:

8.1. Research Questions / Hypotheses:

1.

2.

8.2. Specific Objectives: (State the details of each objective that will finally lead to achievement of the goal)

8.3. Secondary Objectives: (These are subsidiary objectives that could be studied during the course of the project but are not the main objectives of the study, they are optional and vary according to the type of the study)

9. Materials and Methods:

9.1. Study Area/Setting:

9.2. Study Subjects: (Identification and selection, Include Inclusion and exclusion criteria, include flow charts where relevant)

9.3. **Study Design:** (Mention the type of study design e.g., cross-sectional, case-control, intervention study, etc., mention the usefulness/advantages and weaknesses of the design that you have chosen for your study)

9.4. **Sample Size/Statistical Power:** (Mention the input criteria for sample size estimation)

9.5. **Sampling Technique:** (Mention the sampling technique, (e.g. randomization) that will be used to obtain a representative sample for your target population)

9.6. **Study Primary Outcomes:** The primary outcomes should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic, or other) of the study. This is the measure used to answer your study aim. However, it is also the outcome used to calculate study sample size and power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified. Primary outcome measures may be measured in various ways such as: binary (e.g. caesarean/no caesarean, blood loss ≥500mL/blood loss <500mL); continuous (e.g. weight - kg, blood loss - mL); ordinal (e.g. pain - mild, moderate, severe); time to event (e.g. survival), and counts (e.g. number of infections, number of events occurring).

9.7. Data Collection Methods, Data Instruments/Questionnaires used, Measurements: (Describe the instruments used for data collection (questionnaire, observation recording form, etc.), and the variables included in these instruments, as well as the methods used to test for the validity and reliability of the instrument. Techniques used should be briefly described and referenced. Study definitions [e.g., case definition] should be mentioned. What are the variables of most interest? Who will collect the data? How will the data be recorded?)

9.8. Data Management and Analysis Plan: (Describe the analysis plan, tests used for data analysis and statistical package(s) used)

9.9. Protection of Confidentiality:

a) Will all data be coded using numbers or pseudonyms?	Yes/No
b) Will all data collection tools be free of any names or identifiers such as ID numbers?	Yes/No
c) Will all data be stored in a locked file cabinet or password protected computer file?	Yes/No

d) Will only the research team have access to the data?
e) Will you be using photographs, recording or video equipment? Yes / No
f) For how long the data will be stored?
g) How will the data be disposed of? Yes / No
h) Who will have ultimate ownership of the data?

10. Risks and Benefits of the Study:

10.1. Risks to the Participants:

a) Describe possible adverse outcomes/risks that may affect the participants.

(List ALL foreseeable risk to participants. If you are asking questions related to mental or physical health, include the possibility of subjects experiencing such emotions as anxiety or sadness. If the above does not apply, state: "Risks are minimal", which means the risk are no greater than experienced in everyday life. If applicable, include a plan for **Minimization of Risks to Participants** that includes referral to a mental health professional, if the participant requires further emotional support)

b) What is the provision for managing these adverse outcomes?

c) Who will pay for their management?

10.2. Identification of Therapeutic Needs of the Participants: In cases where therapeutic needs of the research participants are identified during the study:

a) What is the provision for managing these needs of the participants?

b) Who will pay for them

10.3. Laboratory and Radiological Studies:

a) In case research participants are also patients at PKLI, will any additional study related tests be performed which are not routinely required as part of the work up for the patient?

b) Who will pay for these additional tests?

10.4. What are actual potential benefits, if any, to be obtained:

a) By the participants?

b) By the society as a result of this study?

c) Benefit of the study to the funding agency or sponsors?

d) Benefit of the study to the institution where study is being conducted?

11. Ethical Considerations: (Please attach Informed Consent and Patient Information Leaflet. Translated forms are to be provided when needed)

11.1. How will you obtain informed consent?

11.2. Where informed consent is unable to be provided, what will you do?

11.3. How will participants be given the opportunity to complain?

11.4. How will you deal with complaints made against you by participants?

11.5. How will you deal with any sensitive or criminal matters that may be raised in the course of your research?

11.6. What follow-up support will be available to participants should they require it?

12. Dissemination of Results/Findings:

12.1. In what form will your findings be presented/disseminated - e.g. report, presentation, journal article, abstract, etc.?

12.2. To whom will you be disseminating your findings?

12.3. Have you thought about intellectual property rights? If applicable, how will you go about ensuring this?

13. Bibliographic References: (Mention recent articles relevant to the study subject and enumerated according to their order of appearance in the text)

14. Workplan: (Please use this form as a template for the timeline of your project)

Tasks/Activities	MONTH											
	1	2	3	4	5	6	7	8	9	10	11	12

15. Funding Details:

Does this study need fund? Yes [ ] No [ ]

Is your study funded by an external funding agency? Yes [ ] No [ ]

(If yes, specify the agency and available funds)

Is indemnity insurance for study participants available? Yes [ ] No [ ] Not applicable [ ]

(If yes, please provide proof (attach a copy of insurance policy or letter of indemnity)

_____

16. Budget:

Budget Breakdown	Unit Cost (PKR)	Total (PKR)	Remarks/Justification
Personnel			
Total			
Supplies and Equipment			
Total			
Patients Cost			
Total			

	Others (please, specify and justify briefly) (including conference fees, publications fees, accommodation and travel expenses, etc.)			
	Total			
	GRAND TOTAL			

17. Appendices: (Please attach the related documents - Data collection instruments, Questionnaires (in Urdu and English), Consent forms in Urdu and English, Participant Information Leaflet, etc.)