INDIAN COUNCIL OF MEDICAL RESEARCH

Model form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(For attachment to each copy of the proposal)

Serial No of IEC Management Office:

Proposal Title:
"Molecular and Biochemical Characterization of Outer Membrane Proteins of *Leptospira* towards Understanding the Pathogenesis of Leptospirosis"

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :							
1. Indian	a) Government	☐	Central	☐	State	☐	Institutional ☐
	b) Private	☐					
2. International	Government	☐	Private	☐	UN agencies	☐	
3. Industry	National	☐	Multinational	☐			
Contact Address of Sponsor:							
Total Budget :							

1.Type of Study :	Epidemiological	☐	Basic Sciences	☐	Animal studies	☐
Clinical:	Single center	☐	Multicentric	☐	Behavioral	☐
2. Status of Review:	New	☐			Revised	☐

3. Clinical Trials:

Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of :

Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). Are you aware if this study/similar study is being done elswhere ?	Yes	No
If Yes, attach details		

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i.	Number of Subjects :		
ii.	Duration of study : 2 years		
iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No
v.	Type of subjects Volunteers ☐ Patients ☐		

vi.	Vulnerable subjects (Tick the appropriate boxes)	Yes ☐	No ☐
	pregnant women ☐	children ☐	elderly ☐
	fetus ☐	illiterate ☐	handicapped ☐
	terminally ill ☐	seriously ill ☐	mentally challenged ☐
	economically & socially backward ☐	any other ☐	
vii.	Special group subjects (Tick the appropriate boxes)	Yes ☐	No ☐
	captives ☐	institutionalized ☐	employees ☐
	students ☐	nurses/dependent ☐	armed ☐
	any other ☐	staff	forces

6. Privacy and confidentiality		
i. Study involves -	Direct Identifiers	☐
	Indirect Identifiers/coded	☐
	Completely anonymised/ delinked	☐
ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials	Yes	No
i. Use of fetal tissue or abortus		
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad ?	Yes	No
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	eg. genetic basis for drug development	

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No

vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

Checklist for attached documents:

Project proposal – 20 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Ethics Committee clearance	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

Place: Signature & Designation of PI/Co-PI/Collaborator
Date: