



अखिल भारतीय आयुर्विज्ञान संस्थान, नागपुर  
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR

Address: Plot No2, Sector 20, MIHAN, Nagpur-441108

Institutional Ethics Committee (IEC)

Department of Pharmacology

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APPLICATION FORM FOR INITIAL REVIEW

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS			
(a) Name of Organization			
(b) Name of Ethics Committee			
(c) Name of Principal Investigator			
(d) Department/Division			
(e) Date of Submission			
(f) Type of review requested: Exemption from Review <input type="checkbox"/> Expedited Review <input type="checkbox"/> Full Committee Review <input type="checkbox"/>			
(g) Title of the study			
Acronym/Short title, (If any)			
(h) Protocol number (If any)		Version number	
(i) Details of Investigators			
Name	Designation & Qualification	Department & Institution	Address for communication
Principal Investigator/Guide			
Co-investigator/student/fellow			
(j) Number of studies where applicant is a: i) Principal Investigator at time of submission <input type="checkbox"/> ii) Co-Investigator at time of submission <input type="checkbox"/>			
(k) Duration of the study:			
2. FUNDING DETAILS AND BUDGET			
(a) Total estimated budget for site			
At Site:	India:	Globally:	
(b) Self-funding <input type="checkbox"/>	Institutional funding <input type="checkbox"/>	Funding agency <input type="checkbox"/>	

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH
(a) Lay Summary of study(within 300 words)

(b) Type of study:		
Basic Sciences <input type="checkbox"/>	Clinical <input type="checkbox"/>	Cross Sectional <input type="checkbox"/>
Retrospective <input type="checkbox"/>	Epidemiological/ Public Health <input type="checkbox"/>	Case Control <input type="checkbox"/>
Prospective <input type="checkbox"/>	Socio-behavioral <input type="checkbox"/>	Cohort <input type="checkbox"/>
Qualitative <input type="checkbox"/>	Quantitative <input type="checkbox"/>	Systematic Review <input type="checkbox"/>
Biological samples/Data <input type="checkbox"/>	Mixed Method <input type="checkbox"/>	Any others ( <i>Specify</i> ) <input type="checkbox"/>
<b>4. METHODOLOGY</b>		
(a) Sample size/ No. of Participants (as applicable)		
At site	In India	Globally
Control group	Study Group	
Justification for the sample size chosen ( <i>100 words</i> ); In case of qualitative study, mention the criteria used for saturation		
(b) Is there an external laboratory/ outsourcing involved for investigations? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>		
How was the scientific quality of the study assessed?		
Independent external review <input type="checkbox"/>	Review by Sponsor/Funder <input type="checkbox"/>	Review within PI's Institution <input type="checkbox"/>
Review within multi-centre research group <input type="checkbox"/>	No Review <input type="checkbox"/>	
Date of review		
Comments of Scientific Committee, if any(100 words)		

### SECTION C - PARTICIPANT RELATED INFORMATION

<b>5. RECRUITMENT AND RESEARCH PARTICIPANTS</b>			
(a) Type of participants in the study:			
Healthy volunteer <input type="checkbox"/>	Patient <input type="checkbox"/>	Vulnerable person/ Special groups <input type="checkbox"/>	Others ( <i>Specify</i> ) <input type="checkbox"/>
Who will do the recruitment?			
Participant recruitment methods used			
Posters/ leaflets/ Letters <input type="checkbox"/>	TV/Radio ads/ Social media/ Institution website <input type="checkbox"/>	Patients / Family/ Friends visiting Hospitals <input type="checkbox"/>	Telephone <input type="checkbox"/>
Others( <i>Specify</i> ) <input type="checkbox"/>			
(b) i. Will there be vulnerable person/special groups involved? Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>			
ii. If yes, type of vulnerable person /special groups			
Children under 18 yrs <input type="checkbox"/>	Pregnant or lactating women <input type="checkbox"/>		
Differently abled (Mental/Physical) <input type="checkbox"/>	Employees/Students/Nurses/Staff <input type="checkbox"/>		
Elderly <input type="checkbox"/>	Institutionalized <input type="checkbox"/>		
Economically and socially disadvantaged <input type="checkbox"/>	Refugees/Migrants/Homeless <input type="checkbox"/>		
Terminally III (stigmatized or rare diseases) <input type="checkbox"/>	Any other ( <i>Specify</i> ): <input type="checkbox"/>		
iii. Provide justification for inclusion/exclusion			
iv. Are there any additional safeguards to protect research participants?			
(c) Is there any reimbursement to the participant? Yes <input type="checkbox"/> No <input type="checkbox"/>			

If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details					
(d) Are there any incentives to the participant?				Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details					
(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?				Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details					
<b>6. BENEFITS AND RISKS</b>					
(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?				Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, categorize the level of risk:					
Less than Minimal risk <input type="checkbox"/>		Minimal risk <input type="checkbox"/>			
Minor increase over minimal risk or Low Risk <input type="checkbox"/>		More than Minimal Risk or High Risk <input type="checkbox"/>			
ii. Describe the risk management strategy:					
(b) What are the potential benefits from the study?			Yes	No	If Yes
For the participant			<input type="checkbox"/>	<input type="checkbox"/>	
For the society/community			<input type="checkbox"/>	<input type="checkbox"/>	
For improvement in science			<input type="checkbox"/>	<input type="checkbox"/>	
Please describe how the benefits justify the risks					
(c) Are Adverse Events expected in the study?				Yes <input type="checkbox"/>	No <input type="checkbox"/> NA <input type="checkbox"/>
Are reporting procedures and management strategies described in the study?				Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Yes, Specify					
<b>7. INFORMED CONSENT</b>					
(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8.				Yes <input type="checkbox"/> No <input type="checkbox"/>	
(b) Version number and date of Participant Information Sheet (PIS):					
Version number and date of Informed Consent Form (ICF):					
(c) Type of consent planned for :					
Signed consent <input type="checkbox"/>	Verbal/ oral consent <input type="checkbox"/>	Witnessed consent <input type="checkbox"/>	Audio-Video (A/V) consent <input type="checkbox"/>		
Consent from LAR (If so, specify from whom) <input type="checkbox"/>	For children < 7 yrs parental/LAR Consent <input type="checkbox"/>	Verbal assent from minor (7-12 yrs) along with parental consent <input type="checkbox"/>	Written Assent from Minor (13-18 yrs) along with parental consent <input type="checkbox"/>		
Other (specify) <input type="checkbox"/>					
(d) Who will obtain the informed consent?					
PI/Co-I <input type="checkbox"/>	Nurse/Counselor <input type="checkbox"/>	Research Staff <input type="checkbox"/>	Other (Specify) <input type="checkbox"/>		
Any tools to be used					
(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)					
English <input type="checkbox"/>	Local language <input type="checkbox"/>	Other (specify) <input type="checkbox"/>			
List the languages in which translations were done					

If translation has not been done, please justify			
(f) Provide details of Consent requirement for previously stored samples if used in the study.			
(g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)			
Simple language <input type="checkbox"/>	Data/ Sample sharing <input type="checkbox"/>	Compensation for study related injury <input type="checkbox"/>	
Risks and discomforts <input type="checkbox"/>	Need to recontact <input type="checkbox"/>	Statement that consent is voluntary <input type="checkbox"/>	
Alternatives to participation <input type="checkbox"/>	Confidentiality <input type="checkbox"/>	Commercialization/benefit Sharing <input type="checkbox"/>	
Right to withdraw <input type="checkbox"/>	Storage of samples <input type="checkbox"/>	Statement that study involves research <input type="checkbox"/>	
Benefits <input type="checkbox"/>	Return of research results <input type="checkbox"/>	Use of photographs/ identifying data <input type="checkbox"/>	
Purpose and procedure <input type="checkbox"/>	Payment for participation <input type="checkbox"/>	Contact information of PI and Member Secretary of EC <input type="checkbox"/>	
Others( <i>Specify</i> ) <input type="checkbox"/>			
<b>8. PAYMENT/COMPENSATION</b>			
(a) Who will bear the costs related to participation and procedures?			
PI <input type="checkbox"/>	Institution <input type="checkbox"/>	Sponsor <input type="checkbox"/>	Other agencies( <i>specify</i> ) <input type="checkbox"/>
(b) Is there a provision for free treatment of research related injuries?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, then who will provide the treatment?			
(c) Is there a provision for compensation of research related SAE? If yes, specify			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Sponsor <input type="checkbox"/>	Institution/ Corpus funds <input type="checkbox"/>	Project grants <input type="checkbox"/>	Insurance <input type="checkbox"/>
(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, specify			
(e) Is there a provision for ancillary care for unrelated illness during the study period?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, please specify.			
<b>9. STORAGE AND CONFIDENTIALITY</b>			
(a) Identifying Information: Study Involves samples/data. If Yes, Specify			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Anonymous/ Unidentified <input type="checkbox"/>	Anonymized <input type="checkbox"/>	Identifiable <input type="checkbox"/>	
	Reversibly coded <input type="checkbox"/>	Irreversibly coded <input type="checkbox"/>	
If identifiers must be retained, what additional precautions will be taken to ensure that access is limited/ data is safeguarded? (E.g. data stored in a cabinet, password protected computer etc.)			
(b) Who will be maintaining the data pertaining to the study?			
(c) Where will the data be analyzed and by whom?			
(d) For how long will the data be stored?			
(e) Do you propose to use stored samples/data in future studies?			Yes <input type="checkbox"/> No <input type="checkbox"/> May be <input type="checkbox"/>
If yes, explain how you might use stored material/data in the future?			

### SECTION D: OTHER ISSUES

<b>10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES</b>	
(a) Will the results of the study be reported and disseminated?	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, specify	
(b) Will you inform participants about the results of the study?	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished?	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes describe in brief ( <i>Max 50 words</i> )	
(d) Is there any plan for post research benefit sharing with participants?	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, specify	
(e) Is there is any commercial value or a plan to patent/IPR issues.	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
If yes, Please provide details	
(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, provide the details	

### SECTION E: DECLARATION AND CHECKLIST

<b>11. DECLARATION (Please tick as applicable)</b>	
<input type="checkbox"/>	I/We certify that the information provided in this application is complete and correct.
<input type="checkbox"/>	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
<input type="checkbox"/>	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
<input type="checkbox"/>	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
<input type="checkbox"/>	I/We declare that the expenditure in case of injury related to the study will be taken care of.
<input type="checkbox"/>	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
<input type="checkbox"/>	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
<input type="checkbox"/>	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
<input type="checkbox"/>	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
<input type="checkbox"/>	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
<input type="checkbox"/>	I/We have the following conflict of interest (PI/Co-PI):
<input type="checkbox"/>	
<input type="checkbox"/>	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:	Signature:
Name of Co-PI:	Signature:
Name of Guide:	Signature:
Name of HOD:	Signature:

## 12. CHECKLIST

Sr. No	Items	Yes	No	NA	Enclosure No.	EC Remarks(If applicable)
<b>ADMINISTRATIVE REQUIREMENTS</b>						
1.	Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Approval of Scientific Committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	EC clearance of other centers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	Agreement between collaborating partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	MTA between collaborating partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8.	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>PROPOSAL RELATED</b>						
12.	Copy of the detailed protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13.	Investigators Brochure (If applicable for drug/biological/device trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15.	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17.	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ Permissions	Required	Not required	Received	Applied dd/mm/yy	EC Remarks
18.	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
19.	DCGI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
20.	HMSC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
21.	NAC-SCRT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
22.	ICSCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
23.	RCGM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
24.	GEAC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
25.	BARC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
26.	Tribal Board	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
27.	Others (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	YES	NO	NA	Enclosure no.	EC remarks
28.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
29.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		