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
Email: iec@aiimsnagpur.edu.in

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 ☐ Expedited Review ☐ Full Committee Review ☐			
(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 ☐ ii) Co-Investigator at time of submission ☐

(k) Duration of the study:

2. FUNDING DETAILS AND BUDGET		
(a) Total estimated budget for site		
At Site:	India:	Globally:
(b) Self-funding ☐	Institutional funding ☐	Funding agency ☐

SECTION B - RESEARCH RELATED INFORMATION

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

(b) Type of study:					
Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioral	☐	Cohort	☐
Qualitative	☐	Quantitative	☐	Systematic Review	☐
Biological samples/Data	☐	Mixed Method	☐	Any others *(Specify)*	☐

4. METHODOLOGY		
(a) Sample size/ No. of Participants (as applicable)		
At site	In India	Globally
Control group	Study Group	
Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for saturation		

(b)Is there an external laboratory/ outsourcing involved for investigations?	Yes ☐ No ☐ NA ☐
How was the scientific quality of the study assessed?	

Independent external review	☐	Review by Sponsor/Funder	☐	Review within PI's Institution	☐
Review within multi-centre research group	☐	No Review	☐		
Date of review					
Comments of Scientific Committee, if any(100 words)					

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS			
(a) Type of participants in the study:			
Healthy volunteer ☐	Patient ☐	Vulnerable person/ Special groups ☐	Others *(Specify)* ☐
Who will do the recruitment?			
Participant recruitment methods used			
Posters/ leaflets/ Letters ☐	TV/Radio ads/ Social media/ Institution website ☐	Patients / Family/ Friends visiting Hospitals ☐	Telephone ☐
Others*(Specify)* ☐			

(b) i. Will there be vulnerable person/special groups involved?	Yes ☐ No ☐ NA ☐
ii. If yes, type of vulnerable person /special groups	

Children under 18 yrs	☐	Pregnant or lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally Ill (stigmatized or rare diseases)	☐	Any other *(Specify)*:	☐

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 ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details					
(d) Are there any incentives to the participant?				Yes ☐ No ☐	
If yes, Monetary ☐ Non-monetary ☐ Provide details					
(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?				Yes ☐ No ☐	
If yes, Monetary ☐ Non-monetary ☐ Provide details					
6. BENEFITS AND RISKS					
(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?				Yes ☐ No ☐	
If yes, categorize the level of risk:					
Less than Minimal risk ☐		Minimal risk ☐			
Minor increase over minimal risk or Low Risk ☐		More than Minimal Risk or High Risk ☐			
ii. Describe the risk management strategy:					
(b) What are the potential benefits from the study?	Yes	No	If Yes	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐
Please describe how the benefits justify the risks					
(c) Are Adverse Events expected in the study?				Yes ☐ No ☐ NA ☐	
Are reporting procedures and management strategies described in the study?				Yes ☐ No ☐	
If Yes, Specify					
7. INFORMED CONSENT					
(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8.				Yes ☐ No ☐	
(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 ☐	Verbal/ oral consent ☐	Witnessed consent ☐	Audio-Video (A/V) consent ☐		
Consent from LAR ☐ (If so, specify from whom	For children<7 yrs parental/LAR Consent ☐	Verbal assent from minor (7-12 yrs) along with parental consent ☐	Written Assent from Minor (13-18 yrs) along with parental consent ☐		
Other *(specify)* ☐					
(d) Who will obtain the informed consent?					
PI/Co-I ☐	Nurse/Counselor ☐	Research Staff ☐	Other*(Specify)* ☐		
Any tools to be used					
(e) Participant Information Sheet(PIS) and Informed Consent Form (ICF)					
English ☐	Local language ☐	Other (*specify*) ☐			
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 ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐	
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐	
Alternatives to participation ☐	Confidentiality ☐	Commercialization/benefit Sharing ☐	
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐	
Benefits ☐	Return of research results ☐	Use of photographs/ identifying data ☐	
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member Secretary of EC ☐	
Others*(Specify)* ☐			

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?			
PI ☐	Institution ☐	Sponsor ☐	Other agencies*(specify)* ☐
(b) Is there a provision for free treatment of research related injuries?			Yes ☐ No ☐ NA ☐
If yes, then who will provide the treatment?			
(c) Is there a provision for compensation of research related SAE? If yes, specify			Yes ☐ No ☐ NA ☐
Sponsor ☐	Institution/ Corpus funds ☐	Project grants ☐	Insurance ☐
(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 ☐ No ☐ NA ☐
If yes, specify			
(e) Is there a provision for ancillary care for unrelated illness during the study period?			Yes ☐ No ☐ NA ☐
If yes, please specify.			

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify			Yes ☐ No ☐ NA ☐
Anonymous/ Unidentified ☐	Anonymized ☐		Identifiable ☐
	Reversibly coded ☐	Irreversibly coded ☐	
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 ☐ No ☐ May be ☐
If yes, explain how you might use stored material/data in the future?			

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES	
(a) Will the results of the study be reported and disseminated?	Yes ☐ No ☐ NA ☐
If yes, specify	
(b) Will you inform participants about the results of the study?	Yes ☐ No ☐ NA ☐
(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished?	Yes ☐ No ☐ NA ☐
If yes describe in brief *(Max 50 words)*	
(d) Is there any plan for post research benefit sharing with participants?	Yes ☐ No ☐ NA ☐
If yes, specify	
(e) Is there is any commercial value or a plan to patent/IPR issues.	Yes ☐ No ☐ NA ☐
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 ☐ No ☐
If yes, provide the details	

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	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.
☐	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.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	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.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	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.
☐	I/We have the following conflict of interest (PI/Co-PI):
☐	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)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4.	Approval of Scientific Committee	☐	☐	☐		
5.	EC clearance of other centers	☐	☐	☐		
6.	Agreement between collaborating partners	☐	☐	☐		
7.	MTA between collaborating partners	☐	☐	☐		
8.	Insurance policy/certificate	☐	☐	☐		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
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	☐	☐	☐		
PROPOSAL RELATED						
12.	Copy of the detailed protocol	☐	☐	☐		
13.	Investigators Brochure (If applicable for drug/biological/device trials)	☐	☐	☐		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ Permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
18.	CTRI	☐	☐	☐		
19.	DCGI	☐	☐	☐		
20.	HMSC	☐	☐	☐		
21.	NAC-SCRT	☐	☐	☐		
22.	ICSCR	☐	☐	☐		
23.	RCGM	☐	☐	☐		
24.	GEAC	☐	☐	☐		
25.	BARC	☐	☐	☐		
26.	Tribal Board	☐	☐	☐		
27.	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.		☐	☐	☐		
29.		☐	☐	☐		