No: IEC/Pharmac/2022/ Date: __/__/___

Annexure III

Application form for Clinical Trials

Title of the study:

Name of Principal Investigator:

SECTION A: DECLARATION AND CHECKLIST

1. 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 if applicable.
☐	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.
☐	If applicable, 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): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: Signature & Date :

Name of Co-PI: Signature & Date:

Name of Guide: Signature & Date:

Name of HOD: Signature & Date:

2. CHECKLIST

S.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 two years	☐	☐	☐		
4	Approval of Scientific Committee	☐	☐	☐		
5	EC clearance of other centres	☐	☐	☐		
6	Agreement between collaborating partners	☐	☐	☐		
7	Insurance policy/certificate	☐	☐	☐		

PROPOSAL RELATED							
8	Copy of the detailed protocol	☐	☐	☐			
9	Investigators Brochure (If applicable for drug/biological/device trials)	☐	☐	☐			
10	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐			
11	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐			
12	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐			
13	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**
14	CTRI	☐	☐	☐		
15	DCGI	☐	☐	☐		
16	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
17		☐	☐	☐		
18		☐	☐	☐		

Signature of PI: