



अखिल भारतीय आयुर्विज्ञान संस्थान, नागपुर

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR

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

Institutional Ethics Committee for Clinical Trial (IECCT)

RegNo.ECR/1392/Inst/MH/2020 Email:iec@aiimsnagpur.edu.in

Department of Pharmacology



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)	
<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 if applicable.
<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"/>	If applicable, 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): 1. 2.
<input type="checkbox"/>	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	<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 two 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 centres	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6	Agreement between collaborating partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

PROPOSAL RELATED						
8	Copy of the detailed protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9	Investigators Brochure (If applicable for drug/biological/device trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12	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"/>		
13	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
14	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15	DCGI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16	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
17		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
18		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Signature of PI: