ZORAM MEDICAL COLLEGE, FALKAWN.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)

***Code No. of IEC:**

* To be filled by IEC Member Secretary

Proposal Title:

	Name, Designation &Qualifications	Departmental Tel Nos. Email ID	Signature
PI/Guide			
Co-PI/Co-Guide 1.			
2.			
3.			

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at Zoram Medical College, Falkawn. The investigators should sign their CV.

Sponsor Information

1. Indian	a)Government b) Private	☐ ☐	Central	☐	State	☐	Institutional ☐
2. International	Government	☐	Private	☐	UN Agencies	☐	
3.Industry	National	☐	Multinational	☐			
4. Contact address of sponsor							
5. Budget							

1. Type of study	Epidemiological	☐	Basic Sciences	☐	Behavioral	☐
	Clinical	☐	Single Centre	☐	Multi centric	☐
2. Status of review	New	☐	Revised	☐		

1. **Clinical trials**
Drug/Vaccines/Device/Herbal Remedies

i. Does the studyinvolve use of

Drugs	☐	Devices	☐	Vaccines	☐
Indian Systems of Medicines/ Alternate systems of Medicine	☐	Any Other	☐	None	☐

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	Yes ☐	No ☐
Permission is obtained?	Yes ☐	No ☐
If yes, copy of permission attached	Yes ☐	No ☐
iv. Is it an Investigational New Drug?	Yes ☐	No ☐
If yes		
a. Investigator's Brochure enclosed	Yes ☐	No ☐
b. Preclinical studies data available (If yes, provide summary)	Yes ☐	No ☐
c. Clinical studies data available (If yes, provide summary)	Yes ☐	No ☐
d. Clinical study is Phase I Phase II Phase III Phase IV	☐	NA ☐
e. DCGI's permission obtained	Yes ☐	No ☐
If yes, copy of letter enclosed	Yes ☐	No ☐

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and 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 (a) Study: (b) Subject participation

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 Yes ☐ No

(Tick the appropriate boxes)

Pregnant Women	☐	Children	☐	Elderly	☐
Fetus	☐	Illiterate	☐	Handicapped	☐
Terminally ill	☐	Seriously ill	☐	Mentally Challenged	☐
Economically & socially backward	☐	Any other	☐		

vii. Specially group subjects Yes ☐ No ☐

(Tick the appropriate boxes)

Captives	☐	Institutionalized	☐	Employees	☐
Students	☐	Nurses/Dependent	☐	Armed Forces	☐
Any Other	☐	Staff	☐		

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

i. Use of fetal tissue or abortus. **If yes** provide details Yes ☐ No ☐

ii. Use of organs or body fluids. **If yes** provide details Yes ☐ No ☐

iii. Use of recombinant/gene therapy products 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 ionizing radiation/radioisotopes Yes ☐ No ☐

If yes, has Bhabha 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, give details and address of collaborators

a. Sample will be sent outside because (Tick appropriate box)
Facility not available in Zoram Medical College, Falkawn ☐
Facility in Zoram Medical College, Falkawn inaccessible ☐
Facility available but not being accessed ☐
If so, reasons

b. Has necessary clearance been obtained Yes ☐ No ☐

8. Consent *Written ☐ Oral ☐ Audio-Visual ☐

i. Patient Information Sheet attached : (Tick the included elements) Yes ☐ No ☐

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 Material biological	☐
Compensation for participation		Benefits if any on future	☐
		Commercialization e.g. Genetic	☐
		Basis for drug development	☐
Compensation for study related injury	☐		
Translation of information sheet in local Language	☐		

ii. If healthy volunteers will be included, information sheet for them Attached Yes ☐ No ☐

iii. Consent form in English	☐	Local Languages	☐
iv. Who will obtain consent? PI-Co-PI	☐	Nurse/Counsellor	☐
Research Staff	☐	Any Other	☐

*If written consent is not obtained, give reasons

9.Will any advertising be done for recruitment of Subjects?
(Posters, flyers, brochure, websites - if so 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? Yes ☐ No ☐

If yes, Minimal or no risk ☐
More than minimum risk ☐
High risk ☐

iii. Is there benefit	a) to the subject?	Yes ☐ No ☐
	Direct ☐	Indirect ☐
	b) to the society	Yes ☐ No ☐

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?	Yes ☐ No ☐
	If yes, reporting will be done to	
	Sponsor ☐ IEC ☐	DSMB ☐
iii.	Is there a plan for interim analysis of data?	Yes ☐ No ☐

12. Is there compensation for injury? Yes ☐ No ☐

If yes, by

Sponsor ☐ Investigator ☐

Insurance Company ☐ Any Other ☐

13.Do you have conflict of interest? Yes ☐ No ☐

(Financial/Non financial)

If yes, specify

Check list for attached documents:

Project proposal-10 copies	☐
Curriculum Vitae of non Zoram Medical College, Falkawn Investigators	☐
Brief description of proposal/summary	☐
Copy of the Protocol/Project and questionnaire (if any)	☐
Investigator's Brochure	☐
Copy of Patient information sheet & Consent form in local language	☐
Copy of Advertisements/Information brochures	☐
DCGI/DBT/BARC clearance if obtained	☐
Copy of Insurance Policy	☐
Copy of Clinical trial agreement	☐
Copy of IEC proforma	☐
Copy of PI undertaking	☐
Copy of Case Report Form	☐

Signature of PI/Guide

Date

Signature of HOD

ZORAM MEDICAL COLLEGE, FALKAWN.

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR / GUIDE.

1. NAME AND CODE NUMBER OF THE PROJECT

2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR

3. OTHER MEMBERS OF THE RESEARCH TEAM

4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE

5. NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOY ARE PI/GUIDE.

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
3. I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them
4. I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
5. I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.
6. I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
7. I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
8. I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
9. I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of Principal InvestigatorDate

ONE PAGE CV

(For Non-**Zoram Medical College, Falkawn.** Investigator)

Last Name	First Name	Middle Initial
Date of Birth (dd/mm/yy):		Sex
Study Site Affiliation (e.g. Principal Investigator/Guide, Co-Investigator/Co-Guide, Coordinator)		
Professional Mailing Address (Include institution name)	Study Sited Address (Include institution name)	
Telephone (Office):	Mobile Number:	
Telephone (Residence):	E-Mail:	

Academic Qualifications (Most current qualification first)		
Degree/Certificate	Year	Institution, Country

Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	Title	Institution/Company, Country

Brief Summary of Relevant Clinical Research Experience:	
Signature: (Signature Required)	Date:

ZORAM MEDICAL COLLEGE, FALKAWN.

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR/GUIDE BY THE MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE

No.F.20016/1/18-ZMC/IEC/_____
Dated: _____

To,

Prof. / Dr. _____

The Institutional Ethics Committee in its meeting held on _____, has reviewed and discussed your application to conduct the clinical trial/project entitled;

_____

_____

_____

sponsored by _____Code no._____

The following documents were reviewed:

a. Trial Protocol (including protocol amendments)/project, dated _____
b.Investigator's Brochure, dated _____.
c.Patient Information Sheet and Informed Consent Form (including updates if any) in Hindi, English and/or vernacular language.
d.Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e.Current CV of investigator from outside Zoram Medical College, Falkawn.
f.Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g.Investigator's Agreement with the Sponsor,
h. Investigator's Undertaking.
i. Ethics Committee Proforma.
j. DCGI approval letter/submission letter, if any.
k.Zoram Medical College, FalkawnCase Report Form
l. Any other/additional documents

Decision of Committee: Institutional Ethics Committee Member Secretary

ZORAM MEDICAL COLLEGE, FALKAWN.

INTIMATION OF START OF STUDY

1. Project/Trial Code Number

2. Title of the drug/multicentric trial

3. Principal Investigator (Name & Department)

4. Sponsor

5. Contract Research Organization (CRO) if any

6. Date of sanction by IEC

7. Date of start

Date:(Signature of Principal Investigator)

ZORAM MEDICAL COLLEGE, FALKAWN.

PROGRESS REPORT (Annual)/FINAL REPORT

1. Project/Trial Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator/Guide (Name & Department)

4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start
8. Objectives of the study
9. Progress report as per objectives (attach separate sheet)
10. Serious Adverse Events if any with details (in summary form)
11. Protocol deviation if any with reasons/justifications
12. Report/publications/conference presentation
13. Awards/recognition

Date: **(Signature of Principal Investigator)**

(Signature of Head of the Department)

ZORAM MEDICAL COLLEGE, FALKAWN.

INFORMED CONSENT FORM

Study Title _____

Study Number _____

Subject's Full Name _____

Date of Birth/Age_____

Address _____

1. I confirm that I have read and understood the information sheet dated_____ for the abovestudy and have had the opportunity to ask questions.**OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Signatory's Name_____ Date_____

Signature of the Investigator _____Date _____

Study Investigator's Name _____ Date _____

Signature of the Witness _____ Date_____

Name of the Witness _____ Date _____

ZORAM MEDICAL COLLEGE, AIZAWL

LIST OF MEMBERS OF ETHICS COMMITTEE

Sl/No	Name	Post
1	Prof. N. Senthil Kumar (Professor, Department of Biotechnology, MZU)	Chairman
2	Dr. Dev Ashis Ramu Damu (Associate Professor, Department of Forensic Medicine & Toxicology, ZMC&H)	Member Secretary
3	Dr C.Vanlalhlua (Professor & HoD, Department of General Surgery, ZMC&H)	Member (Clinician)
4	Dr. Lalromawii (Assistant Professor, Dept. of Pharmacology, ZMC&H)	Member (Basic Medical Science)
5	Mr. Lalhmingsanga Hmar Advocate	Member (Legal Expert)
6	Rev. Dr. Laldingluaia Associate Professor, ATC	Member (Social Scientist)
7	Mr. F. Lalchhanchhuaha Village Council Member, Falkawn Mrs. Vanlalvuani Village Council Memebr, Falkawn Mr. Lalremruata Fanai Falkawn Mr. Ebenezer Lalhruaitluanga MINECO Khatla, Aizawl	Member (Layperson)

8	Dr Manoj B. Pakti (Associate Professor, Department of Community Medicine, ZMC&H)	Member
9	Dr. Swagnik Roy Professor & HoD, Department of Microbiology, ZMC&H	Member
10	Dr. Sangzuala, Associate Professor Department of Community Medicine, ZMC&H	Member
11	Dr. Zothansangi, Professor Department of Pathology, ZMC&H	Member