**MIZORAM UNIVERSITY, AIZAWL**

*Form to be filled by the Principal Investigator (PI) for submission to the Mizoram University Human Ethics Committee (MZUHEC)*

**\*Code No. of MZUHEC:**

\* To be filled by MZUHEC Member Secretary

**Proposal Title:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name, Designation & Qualification | Mobile No. & Email ID | Signature |
| PI/Guide |  |  |  |
| Co-PI/Co-Guide1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). The investigators should sign their CV.

**Sponsor Information**

**1. Indian** a)Government Central State Institutional

 b) Private

**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

1. Does the study involve use of

Drugs Devices Vaccines

Indian Systems Any Other None

of Medicines/

Alternate systems of Medicine

1. Is it approved and marketed

In India UK & Europe USA

Other Countries, Specify

1. 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

1. **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 and the Privacy and confidentiality of maintaining the data** *(Attach the proposal as separate Annexure)*
2. **Subject selection**

i. Number of subjects :

ii. Duration of (a) Study: (b) Subject participation

iii. Will subjects from both sexes be recruited (Tick the appropriate boxes) Yes No

iv. Inclusion/exclusion criteria given Yes No

v. Type of subjects Volunteers Patients

vi. Vulnerable subjects Yes No

Pregnant Women Children Elderly

Fetus Illiterate Handicapped

Terminally ill Seriously ill Mentally

Challenged

Economically & Any other

socially backward

vii. Specially group subjects Yes No

Captives Institutionalized Employees

Students Nurses/Dependent Armed Forces

Any Other Staff

1. **Privacy and confidentiality**
2. Study Involves Direct Identifiers

Indirect Identifiers/Coded

Completely Anonymised /Delinked

1. Confidential handling of data by staff Yes No

**7. Use of biological/hazardous materials**

1. Use of fetal tissue or abortus. **If yes, provide details** Yes No
2. Use of organs or body fluids. **If yes, provide details** Yes No
3. ***Has the permission for sample collection obtained from the respective hospital/ medical centre/ organization/ centre from where the samples are actually going to be collected (provide proof)*** Yes No
4. Use of recombinant/gene therapy products Yes No

**If yes**, has Department of Biotechnology (DBT) approval for rDNA Yes No

products been obtained?

1. Use of pre-existing/stored/left over samples Yes No
2. Collection for banking/future research Yes No
3. Use of ionizing radiation/radioisotopes Yes No

**If yes**, has Bhabha Atomic Research Centre (BARC) approval for Yes No

Radioactive Isotopes been obtained?

1. Use of Infectious/biohazardous specimens Yes No
2. Proper disposal of material Yes No
3. Will any sample collected from the patients be sent abroad? Yes No

**If yes**, give details and address of the collaborators (in the proposal).

Sample will be sent outside because the Facility not available in Mizoram

Give details regarding the experiments to be done outside Mizoram (in the proposal).

Has necessary clearance been obtained from concerned authorities Yes No

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

1. Patient Information Sheet attached : (Tick the included elements)

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

1. If healthy volunteers will be included, information sheet for them

Attached Yes No

1. Consent form in English Local Languages
2. 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**

1. Is the risk reasonable compared to the anticipated benefits to

subjects/community/country? Yes No

1. 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**

1. Is there a data & safety monitoring committee/Board (DSMB)? Yes No
2. Is there a plan for reporting of adverse events? Yes No

**If yes**, reporting will be done to

Sponsor IEC DSMB

1. 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 copy

Curriculum Vitae of Investigators

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 MZUHEC proforma

Copy of PI undertaking

Copy of Case Report Form

Signature of PI/Guide

Date Signature of HOD

 / Director / Dean

ONE PAGE CV

 (Investigators)

|  |  |  |
| --- | --- | --- |
| 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: |

**MIZORAM UNIVERSITY, AIZAWL**

FORMAT FOR PROGRESS REPORT (Annual)/FINAL REPORT for MZUHEC

1. Project/Trial Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator/Guide (Name & Department)
4. Sponsor Information
5. Contract Research Organization (CRO) if any
6. Date and no. of sanction by IHEC
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)**