# *ANNEXURE I*

# Regional Institute of Medical Sciences

# Imphal, Manipur

#### RESEARCH ETHICS BOARD

**APPLICATION FOR ETHICS REVIEW**

**Section I: ADMINISTRATIVE**

### Application No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Receipt**: \_\_\_\_(DD)/\_\_\_\_(MM)/\_\_\_\_\_\_\_(YYYY)

**(A) INVESTIGATORS:***(Attach brief CV of each investigator – not more than 2 pages each)*

|  |  |
| --- | --- |
| **Principal Investigator:** | |
| Name: enter name  Address: enter address | Degree: Click here to enter text. |
| **Co-Principal Investigator(s)** | |
| **(1)** Name: enter name  Address: enter address | Degree: Click here to enter text. |
| **(2)** Name: enter name  Address: enter address | Degree: Click here to enter text. |
| **(3)** Name: enter Name  Address: enter address | Degree: Click here to enter text. |
| **(4)** Name: enter Name  Address: enter address | Degree: Click here to enter text. |
| **(5)** Name: enter Name  Address: enter address | Degree: Click here to enter text. |
| Enter here if more | |

**(B) TITLE AND DURATION OF PROPOSED STUDY:**

|  |
| --- |
| **Study Title:**enter title here |
| **Month and year of likely commencement of the study:**mm/yyyy |
| **Duration of the study:**enter here. |

**(C) FUNDING:**

|  |
| --- |
| **Type of funding:** |
| ☐ Contract/Grant ☐ Subcontract ☐Gift/donation of drugs/devices  ☐ Student Project ☐Other (specify) |
| **Source of funding:** *(If multiple sources, give information on primary source)* |
| ☐**Government:** *specify:*☐*Central*☐*State*☐ *Local*  ☐ **Private Foundation:** *specify:* ☐*Indian*☐*Foreign*  ☐ **Industry:** *specify:*☐*Private*☐*Public*☐ *Other*  ☐ **Other ☐ No funding required** |
| **If multiple sources of funding, give information on secondary source(s):** |
| Click here to enter text. |
| **Status of funding:** |
| ☐Funding awarded/available; ☐Funding partially awarded/available;☐ Fund application pending  ☐No funding application made;☐ No funding required |
| Name, address and tel/fax/email of (primary) sponsor with the name of contact person |
| Click here to enter text. |
| **Budget Details (show fund allocation to various heads)** |
| Click here to enter text. |
| **Are the study subjects protected by insurance coverage?** ☐ **Yes** ☐**No**  If yes, specify the amount and conditions of coverage  Click here to enter text. |

**(D) DRUG, DEVICES AND BIOLOGICS:**

|  |
| --- |
| **Does your study involve testing of drug(s), device(s) and/or biologics?** ☐**Yes** ☐**No** |
| **If yes,**Click here to enter text. |
| **Are they already approved by the regulatory authorities and available in the market or are they new ones?** ☐ **Already approved** ☐ **New one** |
| **Who has prepared and/or is manufacturing the drug(s), device(s) and biologics under investigation?**  Click here to enter text. |
| **Who holds the patent or IND/IDE of the drug(s), Device(s) and biologics under investigation?**  Click here to enter text. |
| **What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective?**  Click here to enter text. |

**(D) PERMISSIONS:***(Attach copy of relevant permission letters)*

|  |  |
| --- | --- |
| **Does your study require permission from regulatory authorities?** ☐ **Yes** ☐ **No** | |
| **If yes, specify the following**: | |
| **(i) From Drug Controller**: ☐ Yes ☐ No. Whether permission obtained: ☐ Yes ☐ No | |
| **(ii) From the ICMR:**☐Yes ☐ No. Whether permission obtained: ☐ Yes ☐ No | |
| **(iii) From other Government department(s)**:  If yes, specify departments:  (a) Dept. Click here to enter text.  (b) Dept. Click here to enter text. | ☐ Yes ☐ No  Whether permission obtained: ☐ Yes ☐No  Whether permission obtained: ☐Yes ☐No |
| Does your study require you to send human biological material outside India? ☐ Yes ☐ No | |
| If yes, have you: | |
| (i) Obtained permission of the Director, RIMS? ☐ **Yes** ☐ **No** | |
| (ii) Has RIMS and the foreign party signed agreement/MoU for that? ☐ **Yes** ☐ **No**  *(if yes, attach a copy of the agreement/MoU)* | |

**(E) STATEMENT ON CONFLICT OF INTERESTS, IF ANY:**

|  |
| --- |
| Describe briefly, if any, the financial and other interests of any of the investigators and/or close relative(s), with the sponsor(s) and outcome of the study.  Click here to enter text. |

**Section II: STUDY DESIGN, SUBJECT/PARTICIPANT SELECTION**

**AND DATA COLLECTION PROCEDURES**

**Note:** As far as possible, complete items A to F given below using non-technical, lay language. Give full form or definition of all *abbreviations and acronyms*. The word limit prescribed is recommendatory, but as far as possible, the total length of items A to E should not exceed five pages or 1500 words.

**(A) STUDY BACKGROUND:**

|  |
| --- |
| Give summary of literature review and rationale for the proposed study: 300 words |
| Click here to enter text. |

**(B) STUDY PURPOSE:**

|  |
| --- |
| Give specific hypothesis, aim/goal and objectives: 200 words |
| Click here to enter text. |

**(C) DESIGN** (check all applicable)

|  |
| --- |
| ☐**Phase – I Trial,**☐ **Phase – II Trial**, ☐**Phase – III Trial**, ☐**Phase –IV Trial**;☐**Randomised,**  ☐**Blinded**,☐ **Case-Control,**☐ **Social Sciences,** ☐ **Case Studies**, ☐**Cross-sectional,**☐ **Cohort,**  ☐**Multi-Centre**. **If Multi-Ce**ntre, coordinating centreenter here  ☐**Qualitative,** ☐**Any other (specify)**Click here to enter text. |
| **Any general description of design** (100 words) |
| Click here to enter text. |

**(D) SUBJECT/PARTICIPANT SELECTION**

|  |
| --- |
| **(a) TYPE: Explain who will be the subjects/participants and rationale for selecting them (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Prisoner, Normal/Healthy volunteer, Student, Staff of the institute). (**100 words) |
| Click here to enter text. |
| **(b) NUMBER: Explain about subject/participant selection** (please respond to each item)**: (i) total number, (ii) rational for having that number or sample size, (iii) sampling method, if any, (iv) what proportion of them will be women, (v) from where they will be recruited and (vi) whether screening of larger number will be required.** (200 words) |
| Click here to enter text. |
| **(c) ELIGIBILITY: Explain Inclusion and Exclusion criteria, with specific explanation if the gender, class, caste, ethnicity, race, will be used as Inclusion and/or Exclusion criteria** (50 words) |
| Click here to enter text. |
| **(d) RECRUITMENT: Explain who will do the recruitment of the subjects/participants and how.** (50 words) |
| Click here to enter text. |

**(E) DATA COLLECTION PROCEDURES:**

|  |
| --- |
| **Explain, in sequence, the conduct of study and all data collection procedures. Please include information on (a) medical/surgical procedures, tests, (b) treatment, (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom. Specify if procedure involves banking of biological samples, HIV testing, genetic testing.** (200 words) |
| Click here to enter text. |

**(F) DATA ANALYSIS:**

|  |
| --- |
| **Plan of data analysis – including by whom and how. Please mention whether data will be analysed to understand gender, caste, class, ethnicity, race differentials.** (150 words) |
| Click here to enter text. |

###### Section III: RISKS, BENEFITS, PRIVACY AND CONFIDENTIALITY

**(A) RISKS:**

|  |
| --- |
| **(a) RISKS, DISCOMFORT AND SIDE EFFECTS: Describe all possible risks and discomfort for subject/participant due to use of intervention and/or interaction procedures/data collection methods proposed. Describe expected degree and frequency of such risk, discomfort, side effect of drug etc.** |
| Click here to enter text. |
| **(b) MINIMISATION: Describe steps you have taken or propose to take to minimise such risk, discomfort or for early recognition of side effects and their management.** |
| Click here to enter text. |
| **(c) DATA AND SAFETY MONIORING:** |
| **i) Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events. Describe Data and Safety Monitoring Plan of your project.**  Click here to enter text.  **ii) Does the project require appointment of an Internal *Data Safety Monitoring Board* (DSMB)? If Yes, suggest 5 or 6 names and addresses of the proposed DSMB members for the REB approval.**  Click here to enter text. |
| **(d) PRIVACY AND CONFIDENTIALITY: Describe (i) how you propose to provide privacy to subjects/participants while conducting study, (ii) what level of confidentiality you propose to promise, (iii) what are the likely consequences to the subject/participant in the event of violation of confidentiality.** |
| Click here to enter text. |
| **(e) IDENTIFIERS: Describe (i) the types of identifiable information on subject/participant you intend to collect, (ii) how do you propose to mask/remove identifiers, (iii) how do you propose to ensure safe keeping and storage of identifiable data.** |
| Click here to enter text. |
| **(f) BENEFITS: Describe benefits to the subject/participant in participating in the study. Also describe the benefits, if any, to the society.** |
| Click here to enter text. |
| **(g) RISK/BENEFIT: Analyse the extent to which the benefits of the study out-weigh the risk to the subjects/participants.** |
| Click here to enter text. |

**Section IV: INFORMED CONSENT PROCESS**

|  |
| --- |
| **(a) TYPE:** (Check all applicable) |
| ☐ Signed witnessed consent; ☐Signed non-witnessed consent; ☐Witnessed Thumb Impression  ☐Non-witnessed thumb impression; ☐Verbal consent; ☐No consent will be obtained  ☐ Consent from Surrogate will be obtained (If so, specify from whom)Click here to enter text. |
| **(b) PROCESS: Describe (i) How, Where, When and By Whom the Informed Consent will be obtained. (ii) how much time the subject/participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, prisoners, etc. (iv) Describe how you will assess that information is correctly understood by the participant.** |
| Click here to enter text. |
| (c) CONTENT OF PARTICIPANT INFORMATION SHEET: Please attach Informed Consent form in English and translated local language(s). The IC form must contain the following information:  (1) a statement that consent is for a study/research/experiment, (2) an explanation of the purpose of research and nature of procedure, (3) all foreseeable risks/discomforts to participants due to research, (4) any benefits to be expected, (5) alternative procedures or courses of treatment in case subject does not want to participate, (6) the extent of confidentiality protection provided, (7) explanation on provision of compensation for injury caused to participant during the study, (8) whom to contact to know more about the study and participants’ rights, (9) a statement that participation is voluntary, (10) A statement that participant can withdraw consent and from the study at any time without any facing any penalty. |
| **(d) INFORMED CONSENT SHEET (ICS): This is the statement signed by the patient or local guardian in case of minor or disabled. It should have the following components**  **1). Pt have read or being read about the patient information sheet (PIS).**  **2). Pt had understood It .**  **3). Agreed to join voluntarily**  **4). Can be withdrawn from the study at any point of time without giving any version and without any penalty / risk.**  **5.) signed in presence of a witness** |
| **e) Assent : In case of minor ,assent form should be submitted in addition to consent form by parent/ legal guardian in presence of a witness** |
| **f) COST AND PAYMENT: Describe the cost for participating in the study to the subject/participant. Describe plan to reimburse or compensate participant – if yes, the amount of payment proposed.** |
| Click here to enter text. |

**LIST OF ATTACHMENTS:**

**1. Full proposal, with protocols/instruments for data collection and budget in detail.**

[The attachments as mentioned in the application form above]

**2.** Click here to enter text.

**3.**Click here to enter text.

**4.**Click here to enter text.

5.Click here to enter text.

**6.**Click here to enter text.

**Principal Investigator's Certification:**

* I certify that the information provided in this application is complete and correct.
* I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
* I will comply with all policies and guidelines of the RIMS REB and affiliated/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.
* I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the RIMS REB approved protocol. I will not modify this RIMS REB certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Date



\*Name and Designation

NOTE: \*To be signed by PI or by the guide in case of student project or by the RIMS investigator in case of non-RIMS PI.

**Annexure II**

**Instruction for filling of application form**

***(General instructions: REB, RIMS normally meets once in the months of February, May, August and November of every year. Application for the proposal should reach the REB*** ***secretariat at least one month before the meeting date. Proposal should be written as far as possible using non-technical language and in simple words. Unqualified use of abbreviations and acronyms should be avoided as far as possible. Keep every part of the write up brief and to the point, but should not be missing any important information. While submitting the proposals, make sure that the following points are included)***

1. Details of the Investigators – Names, addresses, qualification, corresponding investigator (attach CV not more than 2 pages for each of the investigator)
2. Title of the proposed study
3. Funding type and source, status, name and address of the funding agency
4. Budget details
5. Insurance coverage of the participants and investigators and field staff
6. Details of drugs, devices and biological – already approved one, already in use, new one, investigational one, who holds the patent, manufacturer, permission from the concerned authority (like DCGI, ICMR, Govt. agencies, etc), post study availability, any transfer of biological materials within and outside the country and permission, etc
7. Statement of conflict, if any
8. Study Purpose (250 words)

Justification

Hypothesis

Objectives

1. Background of the study (350 words) Relevant literature review

Justification (Rationale of conducting the study)

1. Study Design (Details)
2. Description of study site(s) and duration

i

1. Study participants

Who are the participants? Rationale for selecting them

Eligibility criteria – Inclusion and Exclusion criteria Number of the participants (sample size)

How they are selected (sampling)?

Recruitment of participants; who will do it and how?

1. Description of operational definition or criteria if any
2. Data collection procedure including the instruments and laboratory procedures if any
3. Data analysis – Plan, Who will do it How it will be done
4. List of Risk/Benefit involved in the study. Steps to minimize the risk.
5. How privacy and confidentiality are going to be maintained
6. Data and safety monitoring plan

Definition of SAEs/AEs/SFIs Reporting –

who, whom, when Stopping rules of the study

Summary of data and safety monitoring plan of the study

1. Informed consent process – type and content, who, where, how and when
2. Certification by the Principal Investigator with name, signature and date

I certify that the information provided in this application is complete and correct.

I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.

I will comply with all policies and guidelines of the REB, RIMS and affiliated/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.

I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the REB, RIMS approved protocol. I will not modify this REB, RIMS certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

1. List of the attachments