SIKKIM MANIPAL INSTITUTE OF MEDICAL SCIENCES
SMIMS INSTITUTION ETHICS COMMITTEE

APPLICATION FORM FOR RESEARCH PROJECT PROPOSAL REVIEW

FOR OFFICE USE ONLY: PROPOSAL ID NO: _____

Review type ☐ New ☐ Revised Received on D D M M Y Y Y Y

Review class ☐ Exempted ☐ Expedited ☐ Full Review by ☐ IHREC ☐ IAEEC

Review group ☐ IEC ☐ Ad-hoc members Review on D D M M Y Y Y Y

Signature of Member Secretary

TO BE FILLED IN CAPITAL LETTERS BY PRINCIPAL INVESTIGATOR

PROPOSAL TITLE: _____

Investigators	Name, Designation& Qualifications	Address / Tel & Fax Nos. Email ID	Signature
Principal Investigator			
Co-Investigators			
Curriculum Vitae of Investigators:			

SPONSOR INFORMATION

1. Indian ☐ a. Government ☐ Central ☐ State ☐ Institutional

☐ b. Private

2. International ☐ Government ☐ Private ☐ UN agencies

3. Industry ☐ National ☐ Multinational

Contact address of the Sponsor:

Total Budget:

PROJECT DETAILS:

1. Type of Study : ☐ Epidemiological ☐ Basic Sciences ☐ Animal Studies ☐ Clinical

   ☐ Behavioral ☐ Single Centre ☐ Multicentric

2. Status of Review : ☐ New ☐ Revised

3. Clinical Trials : Drug/Vaccines/Device/Herbal remedies/Others

   i. Does the study involve use of:

   ☐ Drug ☐ Devices ☐ Vaccines

   ☐ ISM / ASM* ☐ Any other ☐ NA

   * ISM – Indian Systems of Medicine / ASM – Alternate Systems of Medicine

   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 permission is obtained? ☐ Yes ☐ No

   If Yes, Date of Permission | D | D | M | M | Y | Y | Y | Y |

   iv. Is it an Investigational New Drug ☐ Yes ☐ No

   If Yes, Investigational New Drug No:

   a. Investigator's Brochure submitted ☐ Yes ☐ No

   b. In vitro studies data ☐ Yes ☐ No

   c. Preclinical studies done ☐ Yes ☐ No

   d. Clinical Study is ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

   e. Are you aware if this study / similar study is being done elsewhere? ☐ Yes ☐ No

   If Yes, attach details.

4. Brief description of the proposal:

5. Subject selection :

i. Number of subjects (sample size) : _____

ii. Duration of the study : _____

iii. Will study 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

☐ Pregnant women ☐ Children ☐ Elderly ☐ Fetus

☐ Illiterate ☐ Handicapped ☐ Terminally ill ☐ Seriously ill

☐ Mentally challenged ☐ Economically & Socially backward ☐ Any other

vii. Special group subjects

☐ Captives ☐ Institutionalized ☐ Employees ☐ Students

☐ Nurses ☐ Armed forces ☐ Dependant staff ☐ Any other

6. Privacy and Confidentiality:

i. Study involves ☐ Direct identifiers ☐ Indirect identifiers / coded ☐ Complete anonymity / delinked

ii. Confidential handling of data by staff ☐ Yes ☐ No

7. Use of Biological / Hazardous materials

i. Use of fetal tissue or abortus ☐ Yes ☐ No

ii. Use of organs or body fluids ☐ Yes ☐ No

iii. Use of recombinant / gene therapy ☐ 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 / radio-isotopes ☐ Yes ☐ No

If Yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? ☐ Yes ☐ No

vii. Use of infectious / bio-hazardous specimens ☐ Yes ☐ No

viii. Proper disposal of materials ☐ Yes ☐ No

ix. Will any sample collected from patients be sent to abroad? ☐ Yes ☐ No

If Yes, justify with details of collaborators.

a. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? ☐ Yes ☐ No

b. Sample will be sent abroad because:

☐ Facility not available in India ☐ Facility in India inaccessible ☐ Facility available, but not being accessed. If so reasons

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

i. If written consent is obtained, tick the included elements listed below.

☐ Understandable language ☐ Benefits ☐ Contact information

☐ Statement that study involves research ☐ Compensation for participation ☐ Statement that consent is voluntary

☐ Sponsor of the study ☐ Compensation for study related injury ☐ Right to withdraw

☐ Purposes and procedures ☐ Alternatives to participation ☐ Consent for future use of biological material

☐ Risks & Discomforts ☐ Confidentiality of records ☐ Benefits if any on future commercialization. Eg. Genetic basis for drug devpt

* If written consent is not obtained, then give reasons.

ii. Who will obtain consent ☐ PI / Co-PI ☐ Research staff ☐ Nurse / Counselor ☐ Others

9. Will any advertising be done for recruitment of subjects? (Posters, flyers, brochures, websites – if so kindly 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 a benefit to ☐ Subject ☐ Society

☐ Direct ☐ Indirect

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

iii. If Yes reporting is done to ☐ Sponsor ☐ Ethics Committee ☐ DSMB

iv. Is there a plan for interim analysis of data? ☐ Yes ☐ No

v. Are there plans for storage and maintenance of all trial databases? If Yes, for how long. ☐ Yes ☐ No

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

If Yes, ☐ Monetary ☐ In kind Specify amount & type: _____

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

If Yes,

☐ By Sponsor ☐ By Investigator ☐ By Insurance Company ☐ By any other

14. Do you have conflict of interest (financial / non-financial) ☐ Yes ☐ No

If Yes, specify: _____

15. Checklist for attached documents:

- ☐ Brief description of proposal
- ☐ Curriculum Vitae of Investigators
- ☐ Patient information sheet
- ☐ Consent form
- ☐ Investigator's brochure for recruiting subjects
- ☐ Copy of advertisements / Information brochures
- ☐ Copy of clinical trial protocol and/or questionnaire
- ☐ Institutional Ethics Committee Clearance
- ☐ Institutional Animal Ethics Committee Clearance
- ☐ CPCSEA clearance, if any.
- ☐ HMSC / DCGI / DBT / BARC clearance if obtained

Place: Signature & Designation of PI

Date:

Please Note: This IEC application form should be forwarded by the Head of the Department to which the Principal Investigator is affiliated.

Signature of the Head

Department of _____

Date: