SIKKIM MANIPAL INSTITUTE OF MEDICAL SCIENCES
SMIMS INSTITUTION ETHICS COMMITTEE

INSTRUCTIONS TO FILL APPLICATION FORM FOR RESEARCH PROJECT PROPOSAL REVIEW

GENERAL INSTRUCTIONS:

1. The application form should be filled handwritten in CAPITAL letters.
2. The application form should be complete in all respect.
3. If space provided is not enough to furnish adequate information, please enclose annexure and mention in the application form at appropriate place.
4. Please enclose necessary documents enlisted in the checklist of the application form for earlier scrutiny. Otherwise proposal review is likely to be delayed.
5. If this is a revised review, do enclose a copy of previous approval letter of SMIMS IEC or CPCSEA whichever applicable.
6. Submit this form with enclosures with a forwarding letter addressed to Chairperson, SMIMS Institution Ethics Committee.

PROPOSAL TITLE:
Write in full the research project title.

INVESTIGATORS DETAILS:
Write the names of Principal and Co-Investigators, Designation & Qualifications. All investigators have to sign in the space provided. Enclose a CV with contact details of all the investigators. Format of CV to be enclosed:

1. Name (Dr./Kum./Smt./Shri) _____
   First name(s) Surname
2. Designation:
3. Complete Postal Address, Telephone Number, Fax, E-mail etc.
4. Date of Birth:
5. Educational Qualification: Degrees obtained (Begin with Bachelor's Degree)

Degree	Institution	Field(s)	Year

6. Research/Training Experience

Duration	Institution	Particulars of work done

7. Research specialization (Major scientific fields of interest).

8. Important recent publications (last 5 years, with titles and References), including papers In press.

9. List out Financial support received from different sources.

SPONSOR INFORMATION
Please tick one or more boxes appropriately. If not applicable please mention NA.
Give complete address of the sponsor of the study and the estimated budget.

PROJECT DETAILS:
1. Type of Study: Please tick one or more boxes appropriately that best describes your research project. If not applicable please mention NA.

2. Status of Review: Please tick either of the boxes.

3. Clinical Trials: Please tick one or more boxes appropriately. If not applicable please mention NA.

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words as annexure)

5. Subject selection: Please tick one or more boxes appropriately. If not applicable please mention NA.

6. Privacy and confidentiality: Please tick one box appropriately. If not applicable please mention NA.

7. Use of biological / hazardous materials: Please tick either of the boxes appropriately. If not applicable please mention NA.

8. Consent: Please tick one box appropriately. If not applicable please mention NA.
   If you have chosen written consent, then tick one or more boxes indicating the elements that were included in the consent form. If you have not chosen written consent, please enclose an annexure explaining the reasons for the same.

9. Will any advertising be done for recruitment of subjects Please tick either of the box appropriately.

10. Risks and Benefit: Please tick either of the boxes appropriately. If not applicable please mention NA.

11. Data Monitoring: Please tick either of the boxes appropriately. If not applicable please mention NA.

12. Is there compensation for participation: Please tick either of the boxes appropriately. If not applicable please mention NA.

13. Is there compensation for injury: Please tick either of the boxes appropriately. If not applicable please mention NA.

14. Do you have conflict of interest (financial / non-financial): Please tick either of the boxes appropriately. If not applicable please mention NA.

15. Check list: Please tick one or more boxes indicating the enclosures.

Please mention Place, Date & Sign the application form.

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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: