

SIKKIM MANIPAL INSTITUTE OF MEDICAL SCIENCES

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INSTITUTION ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE

VERSION 09.01



SMU

Sikkim Manipal University
Health, Medical and Technological Sciences



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SMIMS INSTITUTION ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE

VERSION 09.01

The following SOP Manual for SMIMS IEC received assent from the Vice Chancellor, Sikkim Manipal University on 01st July 2009 and is hereby published for general information.

Dated: 01st July 2009.

A SOP Manual to give effect to the Sikkim Manipal University policy on human subject protection in health sciences research conducted by its faculty, or which involves facilities and/or SMU funding and to provide the constitution of Institution Ethics Committee for regulating conduct of intramural and extramural research on human participants and animal experimentation and the maintenance of SMIMS Research Project Registry and for matters connected therewith or incidental thereto.

WHEREAS SMIMS IEC has actively participated in the ICMR National Survey on functioning of IEC and ICMR has directed the medical institutions conducting research should frame their respective Standard Operating Procedures;

WHEREAS SMIMS is duly registered with CPCSEA for conduct of animal experimentation vide registration number 664/02/a/CPCSEA dated 19th July 2002;

AND WHEREAS it is considered necessary to give effect to the directions of ICMR and CPCSEA to standardize the functioning of SMIMS IEC.

Be it ratified by the ___ Academic Senate duly recommended by DEAN – SMIMS as follows:

CHAPTER I: Introduction:

1. Short title, Extent & Commencement

- 1.1. This manual be called as SMIMS Institution Ethics Committee Standard Operating Procedure Manual (version 09.01) 2009.
 - 1.2. It extends to the faculty and students of Sikkim Manipal Institute of Medical Sciences, the associated Central Referral Hospital, Sikkim Manipal College of Physiotherapy and Sikkim Manipal College of Nursing.
 - 1.3. It shall come into force on such date, the academic senate of Sikkim Manipal University ratifies the manual, upon recommendation by the Dean, Sikkim Manipal Institute of Medical Sciences.
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2. Objectives of Institution Ethics Committee

- 2.1. To ensure the conduct of such research that increases the knowledge in understanding of human health issues in the social context.
 - 2.2. To evaluate the biomedical research project proposals for its scientific validity with respect to research design, methods to analyze data and to ensure the research project complies with the bioethical principles.
 - 2.3. To review the research projects continually so as to ensure the standards of the research protocol, safety and rights of the human participants involved in research, to question the potential conflicts of interest amongst the parties involved in research.
 - 2.4. To ensure the investigator(s) have accountability and transparency in conduct of their research on human participants.
 - 2.5. To direct the investigator(s) meet the compliance and regulations in conduct of research on human participants as prescribed by the Institution Ethics Committee.
 - 2.6. To direct the investigator(s) meet the compliance and regulations in conduct of animal experimentation as prescribed by the CPCSEA.
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3. Terms of SOP

a. Specification

The Standard Operating Procedure Manual shall be specified with the version number (YY:NN) where as YY stands for the year, the SOP is ratified by the Academic Senate, SMU upon due recommendation by DEAN – SMIMS and NN stands for the version. The version is subject to change with respect to the number of times the SOP manual is subject to amendments that are ratified by the Executive Committee upon due recommendation by the members of General Committee as and when necessary. The year mentioned is subject to change at the end of three years from the date of implementation of previous SOP that concurs with the due revision of SOP manual.

b. Validity

The ratified Standard Operating Procedure Manual shall be valid for three years from the date of implementation irrespective of amendments made therein. This time period concurs to the term of the members of Executive and General Committee. The Member Secretary of IEC shall initiate for complete revision of the manual at the end of 32 months so as to incorporate all the amendments made during the term in the revised SOP within four months thereof.

c. Ratification

The Academic Senate of Sikkim Manipal University is authorized to ratify the SMIMS IEC Standard Operating Procedures manual upon due recommendation by the DEAN – Sikkim Manipal Institute of Medical Sciences.

d. Amendments

The Chairperson of IEC is authorized to ratify the amendments of implemented SOP upon due recommendation by at least two-third members of the IEC. However such recommendation cannot amend the constitution of implemented SMIMS IEC SOP. The Member Secretary shall communicate to the DEAN – SMIMS on such amendments made in the review procedures and related matters and shall make it available in the SMIMS Research Project Registry for information.

e. Revision of SOP

The revision of SOP manual shall be done once in three years. At the end of three years, the amendments made therein during the previous term should be forwarded to Academic Senate – Sikkim Manipal University through DEAN – SMIMS for approval.

4. Definitions

In this SOP Manual, unless the context otherwise requires –

- a. Appellate Authority means –
The Vice Chancellor – Sikkim Manipal University or the decision taken by the Vice Chancellor.
- b. “Appropriate Committee” means –
 - i. In relation to the Institution Ethics Committee or the decision taken by the members of the Institution Ethics Committee constituted under sub-section () of section .
 - ii. In relation to the Institution Ethics Sub-committee or the decision taken by the members of the Institution Ethics Sub-committee constituted under sub-section () of section .
- c. “Institution Ethics Committee” means – the Institution Ethics Committee or the decision taken by the members of the Institution Ethics Committee constituted under sub-section () of section
- d. “Institution Ethics Sub-committee” means – the Institution Ethics Sub-committee or the decision taken by the members of the Institution Ethics Sub-committee constituted under sub-section () of section.
 - i. Institution Human Research Ethics Committee (IHREC).
 - ii. Institution Animal Experimentation Ethics Committee (IAEEC).
 - iii. Institution Clinical Ethics Committee (ICEC).
- e. “Consultant” or “Ad-hoc members” means – The members who are identified and appear in the list of ad-hoc members constituted under sub-section () of section and shall be nominated by the Institution Ethics Committee, for the purpose of review of research project proposals specific to the subject area, or in specific context.
- f. “Chairperson” means – the authority appointed under sub-section () of section ().
- g. “Member Secretary” means – the authority appointed under sub-section () of section ()

- h. "Members of the Committee" means –
 - i. In relation to the members of the Institution Ethics Committee appointed under sub-section () of section ().
 - ii. In relation to the members of the Institution Ethics Sub-committee appointed under sub-section () of section ().
 - iii. In relation to the ad-hoc member(s) nominated by the Institution Ethics Committee or the Institution Ethics Sub-committee appointed under sub-section () of section ().

- i. "Research" means – the scientific method of collecting data, analyzing and reasoning health issues in social context.

- j. "Intramural Research" means – the research study being initiated and carried out in the institute by the investigator(s) funded by self, and/or Pharmaceutical companies and/or by the Institute.

- k. "Extramural Research" means – the research study being initiated by the external research institute and being carried out within the institute by the investigator(s) funded by the research agency.

- l. "Collaborative Research" means – the research study being initiated within or outside the institute with a common thrust area identified by the investigators within and outside the institute and concurrently being carried out at more than one location funded by the stakeholders.

- m. "Investigator(s)" means – One or more member of health professional faculty and / or students of health professional courses involved in research study.

- n. "Review" means – In relation to the screening of the research project proposal.
 - i. Exempted Review refers to the research project proposal in which less than the minimal risk associated with research participants.
 - ii. Expedited Review refers to such review, wherein the process is accelerated for:

- proposals which was under full review and is being presented with some modifications or
 - the project in which not more than minimal risk is associated with research participants or
 - project proposal review of IEC members through e-mail or in written form, where the full review meeting of IEC members is likely to take place more than the 15days of the project proposal submission.
- iii. Full Review refers to such review where the research project proposed
- poses more than the minimal risk associated with research participants.
 - Is a drug trial.
 - Involves collecting of large biological samples.
 - Is multi-centric research project.
 - Is international collaborative project.
- o. “Informed consent” means –
- i. In relation to declaration of information; objectives & outcomes of the research project to the research participants to make them understand the benefits and risks associated with participation in the research project.
 - ii. In relation to the voluntariness of the research participant for participation in the research project through signing of the consent form in prescribed format.
- p. “Conflict of interest” means –
- In relation to the intellectual and/or financial conflicts associated with the research project between the stakeholders.
- q. “Compensation” means –
- In relation to the direct or indirect benefits in terms of health care accessibility and/or financial grant provided to the research participants equivalent to the event of adverse outcomes of the research project.

- r. “Confidentiality” means –
In relation to the maintenance of secrecy of research participants personal information that would otherwise inflict harm physically, mentally or socially on research participants.
- s. “SMIMS Research Project Registry” means –
In relation to the contents of the online register that is owned, developed and maintained by the SMIMS Institution Ethics Committee.
- t. “Clinical trial” means –
a research project that aims at finding the effectiveness of a therapeutic intervention.
- u. minimal risk means –
in relation to the anticipated direct or indirect harm that would occur routinely while carrying out the research project (viz. routine interventions, physical & psychological examinations, investigative procedures etc.)
- v. “Prescribed” means –
 - i. In relation to the rules and regulations as specified by the SMIMS Institution Ethics Committee.
 - ii. In relation to the forms and documents specified by SMIMS IEC in specific format.
- w. “Notification” means –
In relation to the directives issued by the SMIMS Institution Ethics Committee to the stakeholder of the research project.
- x. “Funding agency” or “Sponsor” means –
The Government or Private agency (International, National or the Local agency) that provides financial assistance, gives directives and regulates the conduct of research projects identified as thrust areas of research by the respective agency.
- y. “Institution” means -
In relation to the Sikkim Manipal Institute of Medical Sciences.

Chapter II: Constitution of Institution Ethics Committee:

5. Appellate Authority. The Vice Chancellor – Sikkim Manipal University shall be the appellate authority of SMIMS Institution Ethics Committee.

6. Powers of the Appellate Authority.

- a. The Vice Chancellor shall constitute the SMIMS Institution Ethics Committee (on recommendation of DEAN - SMIMS) duly approved by the Academic Senate.
- b. The Vice Chancellor shall be the authority to approve the IEC budget proposal and shall grant financial sanction for the expenses incurred by the Institution Ethics Committee.
- c. The Vice Chancellor shall accept applications from the investigator(s), funding agency and stakeholders (on recommendation of DEAN - SMIMS) regarding the discrepancy in approval decisions of IEC.
- d. The Vice Chancellor (in consultation and recommendation of the DEAN – SMIMS) shall refer the appeal applications to subject experts or independent IEC for opinion.
- e. The Vice Chancellor shall amend, revoke the approval decision of the standing IEC. The decision of Vice Chancellor will be final and binding on standing IEC.
- f. The Vice Chancellor shall propose to the academic senate to dissolve the standing SMIMS IEC and for reconstitution in special circumstances. The special circumstances shall include:
 - i More than fifty percent of investigator(s) of the submitted project proposals during the year submitting appeal applications to review the project proposals independent of standing IEC due to discrepancy in review procedures and approval decision(s) of IEC.
 - ii Misappropriation of financial sanction made available to the SMIMS Institution Ethics Committee.
 - iii Administrative reasons.

7. Composition and appointment of members of IEC.

The Institution Ethics Committee shall comprise of

- a. Chairperson from amongst the persons (external member other than SMIMS faculty or administration) having exemplary experience in

conduct of research studies in health sciences either retired or serving in medical college, hospital, research centers or a person at the level of Joint Secretary and above in the Department of Health and Family Welfare, Government of Sikkim, to be appointed by the Academic Senate – Sikkim Manipal University.

- b. an external member from amongst the persons having exemplary experience in Indian Judicial system to serve as the legal expert, to be appointed by the Academic Senate – Sikkim Manipal University.
- c. an external member from amongst the persons having experience in social science research to be appointed by the Academic Senate – Sikkim Manipal University.
- d. an external member from the Non-Governmental Organization duly recognized by the State/Central Government to be appointed by the Academic Senate – Sikkim Manipal University.
- e. an external member from amongst the faculty - member of basic medical sciences, clinical sciences or allied health sciences having research experience, to be appointed by the Academic Senate – Sikkim Manipal University.
- f. Dean, Sikkim Manipal Institute of Medical Sciences.
- g. Medical Superintendent, Central Referral Hospital – an associated teaching hospital of Sikkim Manipal Institute of Medical Sciences.
- h. a Member Secretary from amongst the SMIMS faculty – member of basic medical sciences, clinical sciences or allied health sciences having research experience, to be appointed by the Academic Senate – Sikkim Manipal University recommended by the Dean – Sikkim Manipal Institute of Medical Sciences.
- i. one internal member, from amongst the faculty - member of basic medical sciences, clinical sciences or allied health sciences having research experience, to be appointed by the Academic Senate – Sikkim Manipal University recommended by the Dean – SMIMS.

8. Eligibility to be appointed as the IEC member

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- a. The Chairperson
 - i. shall have PhD in any field of health sciences with minimum of five years of administrative experience or shall have master degree in

- health sciences with minimum of ten years administrative experience.
 - ii. shall have at least ten publications in any of the indexed national and/or international journals.
 - iii. Formal training on bioethics is desirable.
- b. The Legal expert
- i. Shall have master degree in law with minimum of ten years experience and shall be a registered member in the respective bar council.
 - ii. Shall be above the rank of Senior Advocate in the High Court / District Court.
 - iii. Knowledge and experience related to national and international laws on research and ethical issues is desirable.
- c. The Social Scientist
- i. Shall have at least master degree in social sciences with minimum of ten years experience.
 - ii. Shall be above the rank of associate professor and/or Head of the Department.
 - iii. Shall be the permanent faculty of UGC recognized institution.
 - iv. Shall have minimum of five publications in any of the indexed national and/or international journals.
 - v. Formal training on bioethics is desirable.
- d. The NGO member
- i. Shall have at least bachelor degree.
 - ii. Shall be an executive or general committee member of Non-Governmental organization duly recognized by the State/Central Government.
 - iii. Shall have reasonable knowledge on research ethical issues.
 - iv. Formal training on bioethics is desirable.
- e. The external faculty member
- i. Shall have at least master degree in related areas.
 - ii. Shall be above the rank of Associate Professor in the respective faculty.

- iii. Shall have at least two publications in any of the indexed national and/or international journals.
 - iv. Formal training on bioethics is desirable.
 - f. The Dean – Sikkim Manipal Institute of Medical Sciences.
 - g. The Medical Superintendent – Central Referral Hospital.
 - h. The Member Secretary
 - i. Shall have master degree in health sciences with minimum of five years administrative experience.
 - ii. Shall be above the rank of associate professor and/or Head of the Department of SMIMS/CRH.
 - iii. Shall have at least five publications in any of the indexed national and/or international journals.
 - iv. Formal training on bioethics in desirable.
 - i. The internal faculty member
 - i. Shall have at least master degree in related areas.
 - ii. Shall be above the rank of Associate Professor in the respective faculty.
 - iii. Shall have at least two publications in any of the indexed national and/or international journals.
 - iv. Formal training on bioethics is desirable.
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**9. Term of
Institution Ethics
Committee
members.**

- a. The term of all the members of the Institution Ethics Committee shall not exceed three years. However the term of Dean – SMIMS and the Medical Superintendent – CRH as the members of the Institution Ethics Committee will remain forever.
 - b. In absence of the appropriate persons, the member can continue for the successive term or for the period till appropriate person is identified. In such instances the Member Secretary shall put forward the reasons to the suggestion for an executive member to continue for the successive term and such resolution should be ratified by the Academic Senate – SMU.
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**10. Powers of
Chairperson**

- a. Authority to approve the decision(s) of two-third members (inclusive or exclusive of chairperson himself) of Institution Ethics Committee.
- b. Shall chair all the meetings of Institution Ethics Committee and direct the member secretary in conduct of IEC affairs.
- c. Shall nominate any of the IEC members to chair the meeting in his/her absence.
- d. Shall authorize the Member Secretary for the expedited review of research proposals. However the list of research proposals given expedited review and the reasons thereof should be deliberated in the ensuing IEC meeting by the Member Secretary.
- e. Shall authorize the budget for the functioning of IEC, remuneration and expense claims of the members of Institution Ethics Committee.
- f. Shall authorize the rights to access the IEC documents by IEC member(s), investigator(s) or by the third party upon recommendation by the Member Secretary.
- g. Shall nominate ad-hoc members (subject experts) for review, specific to project proposals on recommendation of the member secretary and acceptance of two-third members of executive committee.

**11. Powers of
Member
Secretary**

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- a. Shall prepare the calendar of meetings of Institution Ethics Committee.
 - b. Shall prepare the agenda of the meetings of Institution Ethics Committee and communicate the same to the members in writing / e-mail at least fifteen days before the schedule of meeting.
 - c. Shall convene the meetings with the concurrence of the Chairperson, as and when necessary.
 - d. Shall record the minutes of the meetings of Institution Ethics Committee.
 - e. Shall maintain all the records and documents of Institution Ethics Committee.
 - f. Shall maintain the contents of SMIMS Research Project Registry.
 - g. Shall maintain the members' profile in the SMIMS IEC forum, authorize and moderate the post(s) by the members, related to research ethical issues in the IEC.
 - h. Shall prescribe rights to access of IEC documents by other IEC members

or the investigator(s) or the third party and such recommendation shall be forwarded to the Chairperson for approval.

- i. Shall present to the members of the IEC the list of research project proposals for review and moderate the discussions thereof.
- j. Shall communicate with the investigator(s) the decision of IEC regarding the project proposal status.
- k. Shall organize professional development programs for the members of IEC and the faculty of SMIMS/CRH for updating of developments related to ethical issues in research studies.
- l. Shall make official representation of SMIMS IEC in all related matters thereof.
- m. Shall present the annual report and term report in the meetings of IEC and the same shall be published in the annual report of SMU.
- n. Shall propose the budget for the functioning of IEC and related matters thereof.
- o. Shall maintain the list of ad-hoc members as subject experts for review and shall recommend the name(s) specific to certain projects for nomination by the Institution Ethics Committee.

**12. Meetings of
Institution Ethics
Committee**

- a. The meetings of the Institution Ethics Committee shall be convened at least once in three months on third Saturday from 14.00 hrs to 17.00 hrs. (Third Saturday of February, May, August, November)
- b. Shall be convened as and when necessary by the Member Secretary with concurrence of the Chairperson.
- c. The meeting shall be suspended / postponed if:
 - i. Minimum Quorum of members is not present.
 - ii. The Chairperson has not nominated a member to conduct the meeting in his absence / non-availability.
 - iii. Third Saturday happens to be a declared holiday or an emergency holiday.

13. Quorum

- a. A minimum of six members should be present in the meeting and such quorum shall include at least three external members for the review decisions and all matters thereof.

14. Attendance of Members.

- a. The member(s) shall make an effort to attend all the meetings.
- b. In case of non-availability, the same shall be confirmed to the Member Secretary at least ten days in advance in writing or by e-mail.

15. Disqualifications.

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- a. Member(s) shall be disqualified if there is established breach of undertaking, confidentiality of review decisions or documents of IEC.
 - b. Member(s) shall be disqualified if he/she engages in canvassing to fellow members of IEC or nominated ad-hoc member(s) for soliciting review decision pertaining to project proposal(s).
 - c. Member(s) shall be disqualified if engaged in contract with the investigator(s), third party with vested interest on research project proposals and/or negotiating and/or accepting bribe in any form.
 - d. Attendance:
 - i. A member should have at least 75% attendance of all the IEC meetings during the calendar year failing which the member is disqualified for the successive year.
 - ii. If a member fails to attend successively for two meetings, the member is disqualified.
 - e. Procedure for disqualification:
 - i. Any member can initiate the proposal for disqualification, removal or termination of another member providing reasons and concrete evidence thereof.
 - ii. The decision of disqualification, removal or termination of a member shall be communicated to the respective member in writing by the Chairperson for possible explanation.
 - iii. After due discussion in the ensuing IEC meeting, the decision for disqualification, removal or termination of a member shall be proposed by the member who initiated the procedure and shall be supported by at least two-third members (excluding the member proposed for disqualification) and approved by the Chairperson.
 - iv. In case, the Chairperson faces disqualification, the Member Secretary shall communicate to the Vice Chancellor, Sikkim Manipal University for approval of the decision of at least two third members of Institution Ethics Committee (excluding the Chairperson).

- v. In case, the Member Secretary faces disqualification, the Chairperson shall initiate the procedure of disqualification and shall get the approval from the Vice Chancellor, Sikkim Manipal University for the decision of at least two third members of Institution Ethics Committee (excluding the Member Secretary).
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**16. Vacation of
Member Seat in
Executive
Committee.**

- a. Under no circumstances the member seat of the Institution Ethics Committee shall remain vacant.
 - b. The Member Secretary shall initiate the procedure for filling up of the vacant post.
 - c. The members of the Institution Ethics Committee shall propose the name(s) of prospective members in the event of the present member(s) being disqualified or terminated.
 - d. The appointment of the member for vacant post shall be made as per Section 6 of this SOP.
 - e. However the member who is being appointed in place of disqualified member shall serve only for the term deemed of the previous member.
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Chapter III: Office of the Institution Ethics Committee

15. Location: The office of the Institution Ethics Committee shall be located within the premises of Sikkim Manipal Institute of Medical Sciences or Central Referral Hospital.

16. Space requirements: The office of the Institution Ethics Committee shall have at least two rooms – Records room and Office room. The Records room shall have at least an area of 225 ft/m². The Office room shall have at least 400 ft/m².

17. Facilities / Infrastructure: The Record room shall be equipped with required furniture for safe custody of the project documents. The Office room shall have at least one computer with internet connection. The office room shall also have scanner, copier, printer and telephone.

18. Staff The Office shall have at least one part time lower division clerk to prepare the documents and to assist the Member Secretary in maintenance of records & documents of project proposals.

19. Remuneration of the IEC Staff & Members:

- a. The Chairperson shall be entitled for Rs.1000/- as honorarium for chairing each of the IEC meetings. All other members shall be entitled for Rs. 500/- as honorarium for participating in each of the IEC meetings.
- b. Apart from the honorarium, the Member Secretary shall receive remuneration of at least Rs.2000/- per month.
- c. The Lower Division Clerk of any of the SMIMS/CRH department shall be deputed for the work of document preparation and he/she shall receive remuneration of at least Rs. 1000/- per month.

20. Maintenance of Records. The Member Secretary shall be responsible for maintenance of all IEC records. The records shall include maintenance of Register of submitted project proposals, Review applications, approval decisions of project proposals, minutes of IEC meetings, IEC letters, remuneration details of IEC members, annual reports and others. All forms, documents and official letters shall be scanned and be archived in a digital format once in a year.

21. Access rights to records and documents.

- a. With due approval of the Chairperson, the Member Secretary shall prescribe the access rights to individual members of the IEC, investigators, funding agencies and other related stakeholders.
- b. The Member Secretary shall ensure confidentiality of investigator(s) personal information during the process of access.
- c. The Member Secretary shall update the access history in the Register of submitted project proposals.

22. Fund allocation for functioning of IEC.

The Member Secretary shall structure the budget proposal for its efficient functioning duly approved by the IEC and shall be recommended by DEAN – Sikkim Manipal Institute of Medical Sciences to the Vice Chancellor – Sikkim Manipal University & the appellate authority of SMIMS IEC for financial sanction.

Chapter IV: Procedure to scrutinize research project proposals:

- 23. Submission of proposals.**
- a. The project proposal review application shall be accepted on all working days by the Office of the Institution Ethics Committee.
 - b. The principal investigator shall submit the duly filled in research project proposal review application to SMIMS IEC in the prescribed format.
 - c. The provision for submission shall also be made available in the SMIMS IEC Research Project Registry.
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- 24. Registration of project proposals.**
- a. Upon submission of research project proposal(s) the investigator shall receive an acknowledgement of the same (either manually or electronically).
 - b. The acknowledgment will confirm the registration of the project proposal impending review bearing the registration number.
 - c. Such registration number will be used to identify and retrieve information of the research project proposal, to track status of approval by the investigators using SMIMS Research Project Registry.
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- 25. Screening of proposals.**
- a. The submitted research project proposal will be processed by the Member Secretary on the type of review procedure deemed for that proposal.
 - b. Such proposal will be reviewed by the members of IEC from ethical perspectives and by the subject experts for scientific validity.
 - c. The Member Secretary shall ensure completeness of the documents attached and shall liaison with investigator(s) for specific information on research project warranted by the members of IEC and the subject experts.
 - d. The review process, decision of IEC and the status of approval shall be communicated to the principal investigator within 20 working days.
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- 26. Types of review procedures.**
- a. Exempted Review – The research project proposal shall be awarded exempted review in such intervention protocols where there is less than the minimal risk associated with research participants.
 - b. Expedited Review – The review process of research project proposal shall be expedited if:
 - i. The research project which was already approved by SMIMS IEC

and is being re-submitted with some modifications of project proposal.

- ii. the project in which not more than the minimal risk is associated with research participants.
 - iii. the review meeting of IEC members is likely to take place more than the 20 working days of the project proposal submission and in such situations review will be done by the IEC members through e-mail or in written form.
- c. Full Review – The research project proposals may warrant full review if:
- i. The research project involves more than the anticipated minimal risk associated with research participants.
 - ii. The research project involves international collaboration.
 - iii. The project has foreseeable potential conflict of interests.

27. Decision making process.

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- a. Upon submission and registration of research project, the process of review begins.
 - b. The member(s) of IEC shall step out of the review process or the meeting if their research project is under scrutiny or if there is potential conflict of interest. Such declaration should be made by the member(s) before the review process begins and shall be recorded.
 - c. In such situations, to maintain a quorum the Member Secretary shall nominate the ad-hoc members (subject experts) as the interim member for that particular project proposal duly approved by the Chairperson.
 - d. The Member Secretary shall identify the research project proposal to be deemed under specific review category.
 - e. The Member Secretary is authorized to grant exempted review of project proposal if it fulfils the prescribed criteria. The details of such research project proposals granted exempted review shall be presented in the ensuing IEC meeting.
 - f. The Member Secretary shall expedite the review if the scheduled IEC meeting is more than the maximum prescribed days (20) for communicating approval decisions of SMIMS IEC. The Member Secretary shall also expedite project proposals which was approved and is being re-submitted with some modifications and for those research projects with less than minimal risk

associated with research participants. In expedited review, the member secretary shall communicate to the members of IEC and the subject experts either by e-mail or in writing to provide review comments. The review comments and the decision of two-third members of IEC will be taken in to consideration for the approval of research project under expedited review.

- g. In scheduled IEC meeting all the project proposals will be considered including that of full review proposals. In such meetings, the decision of two-third members of IEC will be granted approval by the Chairperson.

28. Approval of research project proposals.

- a. Based on the review comments of subject experts in writing or by e-mail and IEC members either in writing, e-mail or the discussions made thereof in the scheduled meetings of IEC, the decision on approval of research project proposals will be made.
- b. All such decisions on approval will be based on the comments on the scientific validity of the proposed research project by the subject experts and consensus of at least two-third members of IEC.
- c. The decision of approval shall be communicated to the Principal Investigator in writing in the prescribed format duly signed by the Chairperson or by the Member Secretary.
- d. As it is made mandatory that all clinical trials should be registered in Clinical Trial Registry of India (CTRI), before the recruitment of the first research participant, the approval of IEC shall be made provisional. Once the investigator registers his/her trial in the CTRI, a copy of registration should be made available to the IEC and final approval of research project proposal could be communicated.

29. Monitoring / Review of approved research projects.

- a. The approved research projects shall be monitored on a regular basis and shall be reviewed for compliance of intervention protocol mentioned therein the research project proposal.
- b. Any deviation of protocol or serious adverse event(s) shall be declared, recorded and explanations to be sought to the Principal Investigator. The approval of research projects shall be revoked anytime during the course of the research project if it does not confirm to the standards and directions of SMIMS IEC. And such decisions shall be communicated to the funding

agency and a notice shall be issued to the Principal Investigator to terminate the research project with immediate effect.

**30. Number of
research projects.**

Any investigator whether principal investigator or co-investigator shall not get associated with more than six research project at any given time.

Chapter V: SMIMS Research Project Registry

- 31. Development and Maintenance of Registry.** The Information and Technology division of Sikkim Manipal University (SMU-IT) shall develop and maintain the online SMIMS Research Project Registry. The link shall be made available in both SMU website as well as on the SMUERP.
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- 32. Contents and Updating of Registry.** The contents of the registry shall be owned by the Member Secretary of SMIMS Institution Ethics Committee. The Member Secretary shall update the contents of the registry from time to time. The contents of the registry shall be:
- a. Structure of Standing SMIMS IEC committee.
 - b. SMIMS IEC Forum (login name and password required).
 - c. List of research project proposals – data shall include the following:
 - i. Date of research project proposal submission to SMIMS IEC.
 - ii. SMIMS IEC Registration Number.
 - iii. CTRI Number.
 - iv. Title of the Research Project.
 - v. Investigator(s) Name and address.
 - vi. Outline of research methodology.
 - vii. Type of review and approval decision (provisional & final).
 - d. Search option.
 - e. Download section – SMIMS IEC review application, forms & documents to be attached with the application, SMIMS IEC Standard Operating Procedure.
 - f. SMIMS IEC members section (login name and password required). This section shall include:
 - i. Calendar of meetings.
 - ii. Archives of minutes of meetings.
 - iii. Archives of research project proposals reviewed by SMIMS IEC.
 - iv. Agenda of the forthcoming IEC meeting that should also enlist details of the proposal to be reviewed.
 - v. Other related documents.
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- 33. Access rights to Registry.**
- a. The third party sources can have access to all the contents of the registry except for the SMIMS IEC Forum and SMIMS IEC Members section for which login name and password shall be required.

- b. In special circumstances the access to more information of specific research projects by the third party sources can be approved by SMIMS IEC.

34. Archiving of Data.

The data contained in the SMIMS Research Project Registry shall be archived once in 6 months.

35. Data shred.

The data once stored in the digital format shall be shredded using special software beyond recovery so that the document could not be retrieved and not be misused by others.

36. Data Transfer.

The data accumulated in the SMIMS Research Project Registry shall be transferred periodically to the base computer and shall be stored in the digital format.

37. Data Retrieval & Security.

The access to the data and other related information shall be duly secured by the Member Secretary by using password and prescribing stringent access rights to the users of the SMIMS Research Project Registry.

38. SMIMS IEC Forum.

- a. An online forum shall be developed and maintained along with the SMIMS Research Project Registry.
 - b. The faculty members of Sikkim Manipal Institute of Medical Sciences, Sikkim Manipal College of Physiotherapy and Sikkim Manipal College of Nursing shall have access to the forum.
 - c. The faculty members shall gain access to the forum using login name and password.
 - d. The Member Secretary shall post issues related to specific research project after blinding the identity of the researcher(s) and invite comments and suggestions specific to an issue.
 - e. The Member Secretary shall be authenticated to moderate all the posts before it is shared in the forum.
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Chapter IV: Appendices.

1. Application form to be submitted to SMIMS IEC for review of research project proposals involving human participants.
2. Application form to be submitted to SMIMS IEC for review of research project proposals involving animal experimentation.
3. Confidentiality agreement form
4. Declaration form for conflict of interest from Investigator(s).
5. Declaration form for conflict of interest from SMIMS IEC members.
6. Review form for SMIMS IEC members.
7. Curriculum vitae format to be submitted by SMIMS IEC members.
8. Appeal form for Redress of investigator(s) on IEC's decisions.
9. Declaration form to report Serious Adverse Events to SMIMS IEC.
10. Prescribed format for communication with investigator(s) regarding SMIMS IEC approval decisions.