SIKKIM MANIPAL INSTITUTE OF MEDICAL SCIENCES

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SMIMS INSTITUTION ETHICS COMMITTEE

Standard Operating Procedure Manual 2020

VERSION (Version 20.01) 2020

Standard Operating Procedure Manual 2020 .
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This Standard Operating Procedure Manual 2020 for SMIMS Institution Ethics Committee received assent from the Vice Chancellor, Sikkim Manipal University on 30th July 2020 and is hereby published for general information.

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SMIMS INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedure Manual 2020

VERSION 20.01

Dated: 06 August 2020.

A Standard Operating Procedure Manual on SMIMS Institutional Ethics Committee (hereinafter referred to as SMIMS IEC SOP) to give effect to the Sikkim Manipal University policy on human subject protection in bio -medical research conducted by its health sciences faculty, or which involves facilities and/or SMU funding and to provide the constitution of Institutional 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 Indian Council of Medical Research (ICMR) national survey on functioning of IEC ; and it has directed the medical institutions conducting research should frame their respective Standard Operating Procedures;

WHEREAS SMIMS is duly registered with the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) , Ministry of Environ ment & Forests – Government of India for conduct of animal experimentation vide registration number 664/PO/RE /S/02CPCSEA dated 16 th Feb 2017;

WHEREAS the Department of Health, Ministry of Health and Family Welfare, Government of India issued a gazette notification vide G.S.R. 72(E) dated 08 th February 2013 directing the ethics committee to have mandatory registration with licensing authority;

AND WHEREAS it is considered necessary to give effect to the directions of ICMR and CPCSEA and MoHFW to standardize the functioning of SMIMS IEC so as to ensure the interests of human and animal subjects involved in research experimentation;

Now, therefore, the University Research Committee of Sikkim Manipal University , in exercise of its powers in constituting specific committee for functioning of specific affairs , hereby ratifies the SMIMS IEC SOP duly recommended by Dean – SMIMS as follows ---

SMIMS INSTITUTION ETHICS COMMITTEE
Standard Operating Procedures Manual 2020

TABLE OF CONTENTS

Chapter 1: Introduction

1. Title, Scope and Commencement

1.1 The name of the committee will be referred to as SMIMS Institutional Ethics Committee and abbreviated as SMIMS IEC.

1.2 This manual is to be referred as SMIMS Institutional Ethics Committee Standard Operating Procedure Manual 2020 (Version 20.01) and should be abbreviated as SMIMS IEC SOP 2020.

1.3 It extends to clinicians, faculty and students across all health sciences disciplines of constituent units of Sikkim Manipal University viz. Sikkim Manipal Institute of Medical Sciences, Sikkim Manipal College of Physiotherapy, Sikkim Manipal College of Nursing and constituent departments.

1.4 It shall come into force on such date the University Research Committee of Sikkim Manipal University ratifies the manual, upon recommendation by the Dean, Sikkim Manipal Institute of Medical Sciences.

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2. Mandates and Objectives of Institutional Ethics Committee

2.1 Review and approval of research projects :

a. To evaluate the biomedical research project proposals of faculty and students for its scientific validity with respect to research design, methods to analyze data and to ensure the research project complies with the bioethical principles.

2.2 Follow-up and renewal of approval of research projects :

a. 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 stakeholders involved in research.
b. To ensure the investigator(s) have accountability and transparency in conduct of their research on human participants.
c. To direct the investigator(s) meet the compliance and regulations in conduct of research on human participants as prescribed by the Institutional Ethics Committee.
d. To direct the investigator(s) meet the compliance and regulations in conduct of animal experimentation as prescribed by the CPCSEA.

2.3 Training programs

a. To train the faculty and students of health sciences discipline on research methods and facilitate them to undertake various research studies that increases the knowledge in understanding of human health issues in the social context.
b. To sensitize the faculty and students on possible ethical issues in the arena of clinical and research practice .
c. To train the faculty and students on writing skills for grants, journal publications, dissertation and th eses.

2.4 Research Unit / IEC Repository

a. To maintain the knowledge repository pertaining to research methodology, bioethics (both digital and print).
b. To maintain the repository on national/international ethical guidelines on biomedical research.

2.5 Review of f aculty publications:

a. To review all publications of faculty in the books and journals for potential conflict of interest and validate the publication for credit points / incentives as per the SMIMS policy on research incentive.
b. To validate such publications for evaluation in performance appraisals of faculty for possible promotion and/or performance based incentives.
c. To monitor and review any complaint on publication misconduct; and recommend possible disciplinary a ction(s) agai nst erring faculty.

2.6 SMIMS IEC Registry

a. To facilitate online processing of research project proposals for review and approval of SMIMS IEC.
b. To maintain the information on the list of research project proposals reviewed and decisions of the committee there of; the minutes of meetings; the training programs; the curriculum vitae of the IEC members, so on and so forth.

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3. Terms of SMIMS IEC SOP

3.1 Specification

a. The Standard Operating Proced ure Manual will be specified with the version number (YY:NN) where YY stands for the year and NN for the updated version.

b. The version number NN is subject to change with respect to the number of times the SOP manual is subject ed to amendments by IEC as and when necessary.
c. The year mentioned is also subject to change at the end of three years from the date of implementation of previous SOP that concurs with the term of the standing IEC and also the due period for revision of SOP manual.

3.2 Validity:

a. The tenure of SMIMS IEC is for the period of three years so is the SOP manual.
b. The Standard Operating Procedure Manual and the amendments made therein during the tenure of standing SMIMS IEC shall be valid only during that tenure.
c. At the end of the tenure, the re- constituted SMIMS IEC shall scrutinize the SOP and shall recommend to the SMU University Research Committee for approval on any changes made thereof.
d. The Member Secretary of IEC shall initiate for c omplete revision of the manual at the end of 34 months so as to incorporate all the amendments made during the term in the revised SOP within two months thereof.

3.3 Revisions and Updating of IEC SOP:

a. The University Research Committee of SMU shall dissolve the present constitution (if deemed necessary) and/or revise the constitution of SMIMS IEC as and when necessary and in accordance with the directions of the licensing authority viz. CDSCO and DCGI, Ministry of Health and Family Welfare.
b. Except for the con stitution of SMIMS IEC, the Chairperson of IEC shall recommend amendments to the implementation of mandates favored by at least two - thirds of committee members as and when necessary; however such amendments should be endorsed by the SMU University Research Committee
c. The SOP manual shall be revised once in three years along with the term completion of the standing IEC. The revised manual shall be updated with all amendments made therein during the previous tenure.

3.4 Ratification of SMIMS IEC SOP:

The University Research Committee of SMU is authori zed to ratify the SMIMS IEC SOP and any amendments made thereof upon due recommendation by the Chairperson of SMIMS IEC favored by at least two -third members of the IEC.

4. Abbreviations

CDSCO – Central Drugs Standard Control Organization

CoI – Conflict of Interest

CPCSEA – Committee for the Purpose of Control and Supervision of Experiments on Animals .

CRH – Central Referral Hospital

CTRI – Clinical Trial Registry of India

DBT – Department of Biotechnology

DCGI – Drugs Controller General of India DHR

– Department of Health Research, ICMR

DSMB – Data and Safety Monitoring Board

G.S.R – General Statutory Rules (referred in Gazette Notification)

GoI – Government of India

ICF – Informed Consent Form

ICMR – Indian Council of Medical Research

IEC – Institutional Ethics Committee

MoHFW – Ministry of Health and Family Welfare

NGO – Non Governmental Organization

SAE – Serious Adverse Events

SMCoN – Sikkim Manipal College of Nursing

SMCPT – Sikkim Manipal College of Physiotherapy

SMIMS – Sikkim Manipal Institute of Medical Sciences

SMU – Sikkim Manipal University

SOP – Standard Operating Procedures

5. Definitions

In this SOP Manual, unless the context otherwise requires–

5.1 " Appellate Authority " means –

a. In relation to t he University Research Committeeof Sikkim Manipal University or its decisions;
b. In relation to the Vice Chancellor, Sikkim Manipal University or the decision taken by the Vice Chancellor.

5.2 "Appropriate Committee" means –

a. In relation to the Institutional Ethics Committee or the decision taken by the members of the Institutional Ethics Committee .

5.3 "Institutional Ethics Committee" means – the Institutional Ethics Committee itself or the decision taken by the members of t he Institutional Ethics Committee.

5.4 "Institutional Ethics Sub- committee" means – the Institutional Ethics Sub –committee itself or the decision taken by the members of the Institutional Ethics Sub -committee .

5.5 "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 Institutional Ethics Committee, for the purpose of review of research project proposals specific to the subject area, or in specific context.

5.6 "Chairperson" means – the authority as appointed

5.7 "Member Secretary" means – the authority as appointed

5.7.1 Assisstant Member Secretary is required to assist Member secretary and especially in her /his absence to run the proceedings in smooth manner and carry forward duties in stipulated time frame.

5.8 "Members of the Committee" means –

a. In relation to the members of the Institutional Ethics Committee as appointed
b. In relation to the members of the Institutional Ethics Sub-committee as appointed

5.9 " Biomedic al Research" means – the scientific method of collecting data, analyzing and reasoning health issues in social c ontext.

a. " Intramural Research" means – the research study being initiated and carried out in the institute by the investigator(s) funded by self, and/or by the Institute.
b. " 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 and/or Pharmaceutic al comp anies.
c. "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 loc ati on funded by the stakeholders.

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

5.11 "Review" means – In relation to the screening of the research project proposal.

a. " Exempted Review " refers to the research project proposal in which less than the minimal risk associated with research participants.
b. " Expedited Review " refers to such review, wherein the process is a ccelerated for:
    i) proposals which was under fu ll review and is being presented with some modifications or
    ii) the project in which not more than minimal risk is associated with research participants or
    iii) project proposal review of IEC members through e - mail or in written form, where the full review meetin g of IEC members is likely to take place more than the 15 working days of the project proposal submission.
c. "Full Review" refers to such review where the research project proposed
    i) poses more than the minimal risk associated with research participants.
    ii) Is a drug trial.
    iii) Involves collecting of large biological samples.
    iv) Is multi-centric research project.
    v) Is international collaborative project.

5.12 “Informed consent” means –

a. In relation to declaration of information; objectives & expected outcomes of the research project to the research participants to make them understand the benefits and risks associated with participation in the research project.
b. In relation to the voluntar iness of the research participant for participation in the research project through signing of the consent form in prescribed format.

5.13 “Conflict of interest” means –

In relation to the vested interest(s) in claiming intellectual, and/or financial/non -financial benefits by the investigators, sponsors or other stakeholders associated with the research project .

5.14 “Compensation” means –

In relation to the direct or indirect benefits in terms of health c are a ccessibility and/or financial grant / non -financial benefits provided to the research part icipants for the time spent or loss of income or the expenditure incurred for visit to the facility; or in relation to the extent of adverse outcomes (injury to the subject) of the research project.

5.15 “Confiden tiality” 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.

5.16 “SMIMS Research Project Registry” means –

In relation to the contents of the online register that is owned, developed and maintained by the SMIMS Institutional Ethics Committee.

5.17 “Clinical trial” means –

a research project that aims at finding the effectiveness of a therapeutic intervention.

5.18 “ 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 exami nations, investigative procedures etc.)

5.19 “Prescribed” means –

a. In relation to the rules and regulations specified in the SMIMS IEC SOP Manual.
b. In relation to the directions specified by the national / international guidelines or directives of the licensing authority.
c. In relation to the decisions by the SMIMS Institutional Ethics Committee.
d. In relation to the forms and documents specified by SMIMS IEC in specific format.

5.20 “Notification” means –

a. In relation to the directives issued by the SMIMS Institutional Ethics Committee to the stakeholder of the research project.
b. In relation to the directives issued by the licensing authority to the IEC.

5.21 “Funding agency“ or “Sponsor” means –

The Government or Private agency (International, National or the Local agency) that provides financial assistance, gives directives for the conduct of research projects identified as thrust areas of research by the respective agency.

5.22 “Institution” means –

In relation to Sikkim Manipal Institute of Medical Sciences and other constituent units of Sikkim Manipal University .

Chapter 2: Constitution of Institution Ethics Committee

6. Appellate Authority

The University Research Committee of Sikkim Manipal University chaired by the Hon'ble Vice Chancellor of the varsity shall be the appellate authority of SMIMS Institutional Ethics Committee.

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7. Powers of the appellate authority

7.1 The University Research committee of SMU shall approve the constitution and appointment of members to the SMIMS Institutional Ethics Committee (on recommendation of Dean - SMIMS).

7.2 The University Research Committee of SMU will be sole authority to sanction approval for SMIMS IEC SOPand the amendments made therein during the tenure of standing IEC.

7.3 The University Research Committee of SMU shall be the authority to approve the IEC budget proposal and shall grant financial sanction for the expenses incurred by the Institutional Ethics Committee.

7.4 The University Research Committee of SMU shall review applications from the investigator(s), funding agency and stakeholders (on recommendation of Dean - SMIMS) regarding the discrepancy in approval decisions of IEC.

7.5 The University Research Committee of SMU (in consultation and recommendation of the Dean SMIMS) shall refer the appeal applications to subject experts or independent IEC for opinion.

7.6 The University Research Committee of SMU shall amend, revoke the approval decision of the standing IEC. The decision of the University Research Committee will be final and binding on standing IEC.

7.7 The University Research Committee of SMU shall dissolve the standing SMIMS IEC and shall reconstitute IEC in special circumstances. The special circumstances shall include:

a. More than fifty percent of investigator(s) of the submitted project proposals during the year submit ting appeal applications to review the project proposals independent of standing IEC due to discrepancy in review procedures and approval decision(s) of IEC.

b. Misappropriation of financial sanction made available to the SMIMS Institutional Ethics Committee.
c. Directives of the licensing authority to change the standing IEC.
d. Administrative reasons.

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8. Composition of SMIMS IEC

8.1 The Institutional Ethics Committee shall comprise of eight to fifteen members as follows:

a. ONE 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.

b. ONE Member Secretary from amongst the SMIMS faculty – member of basic medical sciences, clinical sciences or allied health sciences having research experience, to be nominated by the Dean –SMIMS.

c. ONE external member from amongst the persons having exemplary experience in Indian Judicial system to serve as the legal expert.

d. ONE external member from amongst the persons having experience in social science research .

e. ONE external member from the Non-Governmental Organization duly recognized by the State/Central Government .

f. Three to seven internal members from amongst the faculty of basic medical sciences, clinical sciences and allied health sciences having research experience, to be nominated by Dean - SMIMS.

8.2 In case of unavailability of members as specified under clause 8.1 (a- f) above, the University Research Committee of SMU on its discretion shall relax the specification(s) to accommodate the existing human resource to be appointed as the member(s) of the IEC.

9. Eligibility to be appointed as IEC member

9.1 The Chairperson

a. 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.
b. shall have at least six publications in any of the indexed national and/or international journals.
c. Formal training on bioethics.

9.2 The Member Secretary

a. Shall have master degree in health sciences with minimum of five years administrative experience.
b. Shall be at or above the rank of Associate Professor and/or Head of the Department of SMIMS/CRH.
c. Shall have at least four publications in any of the indexed national and/or international journals.
d. Formal training on bioeth ics.

9.2.1 Asst member secretary shall have at least master degree/PhD in related areas. Shall have at least two publications in any of the indexed natio nal and/or international journals. Formal train ing on bioeth ics.

9.3 The Legal Expert

a. Shall have master degree in law with minimum of ten years experience and shall be a registered member in the respective bar council.
b. Shall be at or above the rank of Senior Advocate in High Court / District Court / Sessions Court.
c. Knowledge and experience related to national and international laws on medico -legal and/ or research issues is desirable.

9.4 The NGO member

a. Shall have at least bachelor degree.
b. Shall be an executive or general committee member of Non-Governmental organization duly recognized by the State/Central Government.
c. Shall have reasonable knowledge on research ethical issues.
d. Formal training on bioethics is desirable.

9.5 The Social Scientist

a. Shall have at least master degree in social sciences with minimum of five years experience in social scie nce research .

b. Shall have minimum of two publications in any of the indexed national and/or international journals.
c. Formal training on bioethics is desirable.

9.6 Internal members

a. Shall have at least master degree in their respective disciplines .
b. Shall be at or above the rank of Associate Professor in the respective faculty.
c. Shall have at least two publications in any of the indexed national and/or international journals.
d. Formal training on bioethics.

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10. The term of appointment of IEC members

10.1 The term of appointment of all the members of the Institution Ethics Committee shall not exceed three years.

10.2 In absence of the appropriate persons, the member will be re-appointed 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 a member to continue for the successive term and such resolution should be ratified by the University Research Committee – SMU.

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11. Powers of Chairperson, IEC

11.1 Authority to approve the decision(s) of two -third members of Institutional Ethics Committee.

11.2 IEC Meetings:

a. Shall chair all the meetings of Institution Ethics Committee and direct the Member S ecretary in c onduct of IEC affairs.
b. Shall nominate any of the IE C members to chair the meeting in his/her absence.

11.3 Shall scrutinize and approve the list of exempted and expedited review of research proposals on recommend - dation of Member Secretary (which was subjected to review of subject experts and IEC members) .

12. Power of Member Sec.	12.1	Shall act as liaison between the IEC and the licensing authority.
	12.2	Shall apply/prepare the necessary reports for registration and renewal of the registration of IEC for review by the licensing authority.
	12.3	Shall prepare the calendar of meetings of Institutional Ethics Committee.
	12.4	Shall prepare the agenda of the meetings of Institutional Ethics Committee and communicate the same to the members in writing / e -mail at least ten days before the schedule of meeting.
	12.5	Shall convene the meetings with the concurrence of the Chairperson, as and when necessary.
	12.6	Shall record the minutes of t he meetings of Institutional Ethics Committee.
	12.7	Shall maintain all the records and documents of Institutional Ethics Committee.
	12.8	Shall maintain the contents of SMIMS Research Project Registry.
	12.9	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.
	12.10	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 t o the Chairperson for approval.

12.11 Shall organize professional development prog rams for the members of IEC, the health sciences fa culty and students of SMIMS/CRH for sensitization and updating of recent trends on ethical issues in research studies.

12.12 Shall make official representation of SMIMS IEC in all related matters thereof.

12.13 Shall present the annual report and term report in the meetings of IEC

12.14 Shall propose the budget for the functioning of IEC and related matters thereof.

12.15 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 Institutional Ethics Committee.

13.1 The meetings of the Institutional Ethics Committee shall be convened at least once in two months.

13.2 Shall be convened as and when necessary by the Member Secretary with concurrence of the Chairperson.

13.3 The meeting shall be suspended / postponed if minimum Quorum of members is not present.

14. Attendance

14.1 The member(s) shall make an effort to attend all the meetings.

14.2 Minimum of four out of six scheduled meetings (if not the interim meetings convened as and when necessary) should be attended by a member during the one year period.

14.3 In case of non-availability, the same shall be confirmed to the Member Secretary at least five days in advance in writing or by e-mail.

A minimum of six members should be present in the meetings to discuss and approve the meeting agenda; and such quorum shall include at least two external members for the review decisions and all matters thereof.

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15. Quorum

16. Disqualification

16.1 Member(s) shall be disqualified if there is established breach of undertaking, confidentiality of review decisions or documents of IEC.

16.2 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).

16.3 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.

16.4 Attendance:

a. A member should have attended at least four of the six yearly scheduled meetings or 75% of overall IEC meetings held in a year inclusive of interim meetings of IEC during the calendar year failing which the member is disqualified for the successive year.
b. If a member fails to attend successively for two meetings without a valid reason, the member is disqualified.

16.5 Procedure for disqualification:

a. Any member can initiate the proposal for disqualification, removal or termination of another member providing reasons and concrete evidence thereof.
b. 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.
c. 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.
d. 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 Institutional Ethics Committee (excluding the Chairperson).
e. In case, the Member Secretary faces disqualification, the Chairperson shall initiate the procedure of disqualification and shall communicate to the Vice Chancellor, Sikkim Manipal University for approval of the decision of at least two third members of Institutional Ethics Committee (excluding the Member Secretary).

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17. Vacancy of seat of IEC member

17.1 Under no circumstances the seat of the IEC member as mandated in CDSCO requirement, shall remain vacant.

17.2 The Member Secretary shall initiate the procedure for filling up of the vacant post.

17.3 The members of the Institutional Ethics Committee shall propose the name(s) of prospective members in the event of the present member(s) being disqualified or terminated.

17.4 The appointment of the member for vacant post shall be made as per Section 9 of this SOP.

17.5 However the member who is being appointed in place of disqualified member shall serve only for the term deemed of the previous member.

Chapter 3 : Office of the Institution Ethics Committee

18. Address of IEC office	All communications postal or e -mail will be addressed to: The Member Secretary, SMIMS Institution Ethics Committee, Sikkim Manipal Institute of Medical Sciences, 5th Mile, Tadong, Gangtok, East Sikkim – 737102. Phone: 03592 270294 / 270534. Ext: 442. Fax: 03592 231496. E-mail: deanresearchsmims@gmail.com
19. Location, Facilities / Infrastructure	The office of the SMIMS IEC shall be located within the premises of Sikkim Manipal Institute of Medical Sc iences. The premises of SMIMS IEC shall have atleast two rooms' viz. records room and office room. 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 c onnection. The office room shall also have scanner, copier, printer and telephone.
20. Support 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 rec ords & documents of project proposals.
21. Remuneration of IEC staff & members.	21.1 All IEC external members shall be entitled for Rs. 2000/- as honorarium for participating in each of the IEC meetings. 21.2 The Member Secretary shall not receive any honorarium for participation in the IEC meetings. 21.3 The Lower Division Clerk of any of the SMIMS/CRH department shall be deputed for the work of document preparation and will be paid as per the pay scale of the organisation.
22. Maintenance of Records	22.1 The Member Secretary shall be responsible for maintenance of all IEC records. The records shall include a. Research project proposal register. b. Annual calendar of IEC meetings.

c. Minutes of IEC meetings.
d. Attendance register of IEC meetings.
e. Circulars / Notices from/to IEC office.
f. List of resources in IEC repository.
g. Communication of IEC decisions to investigator(s).
h. Registration details of IEC with licensing authority.
i. Compliance reports of IEC on inspection reports of licensing authority.
j. Training programs of IEC members, faculty and students.
k. Curriculum vitae of IE C members (standing & past committees).
l. Access reports of IEC archives.
m. Annual reports submitted to University Research Council – SMU.
n. Remuneration details of IEC members.

22.2 All forms, documents and official letters shall be scanned and be archived in a digital format from time to time .

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23. Access rights to records and documents

23.1 With due approval of the Chairperson, the Member Secretary shall prescribe the access rights to the licensing authority, individual members of the IEC, investigators, funding agencies and other related stakeholders.

23.2 The Member Secretary shall ensure conf identiality of investigator(s) / research study subject(s) personal information during the process of access.

23.3 The Member Secretary shall update the access history in the Register of submitted project proposals.

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24. Fund allocation for functioning of IEC

The Member Secretary shall structure the budget proposal for IEC for its efficient functioning duly recommended by the Chairperson of IEC to the Dean – Sikkim Manipal Institute of Medical Sciences for financial sanction.

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25. IEC Repository

25.1 The office of IEC shall also host the resources pertaining to national / international guidelines, books, journals, media on research / clinical ethics.

25.2 The repository shall be made accessible to all IEC members, health sciences faculty and students.

25.3 The IEC repository shall also host all publications of health sciences faculty during their tenure at SMIMS.

Chapter IV: Procedure to scrutinize research project proposals

26. Submission of research project proposals

26.1 The project proposal review application shall be accepted on all working days by the Office of the Institutional Ethics Committee.

26.2 The principal investigator shall submit the duly filled in research project proposal review application to SMIMS IEC in the prescribed format.

26.3 The provis ion for submission shall also be made available in the SMIMS IEC Research Project Registry.

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27. Registration of research project proposals

27.1 Upon submission of research project proposal(s) the inve stigator shall receive an acknowledgement of the same (either manually or electronically).

27.2 The acknowledgment will confirm the registration of the project proposal impending review bearing the registration number.

27.3 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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28. Screening of research project proposals

28.1 The submitted research project proposal will be processed by the Member Secretary on the type of review procedure deemed for that proposal.

28.2 Such proposal will be reviewed by the members of IEC from ethical perspectives and by the subject experts for scientific validity.

28.3 The Member Secretary shall ensure completeness of the documents attached and shall lia ise with investigator(s) for specific information on research project warranted by the members of IEC and the subject experts.

28.4 The review process, decision of IEC and the status of approval shall be communicated to the principal investigator within 20 working days.

29. Type of Review Procedures

29.1 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.

29.2 Expedited Review – The review process of research project proposal shall be expedited if:

a. The research project which was already approved by SMIMS IEC
b. and is being re-submitted with some modifications of project proposal.
c. the project in which not more than the minimal risk is associated with research participants.
d. 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.

29.3 Full Review – The research project proposals may warrant full review if:

a. The research project involves more than the anticipated minimal risk associated with research participants.
b. The research project involves international collaboration.
c. The project has foreseeable potential conflict of interests.

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30. Decision Making Process

30.1 Upon submission and registration of research project, the process of review begins.

30.2 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.

30.3 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.

30.4 The Member Secretary shall identify the research project proposal to be deemed under specific review category.

30.5 The Member Secretary is authorized to grant exempted review of project proposal if the proposed project poses no minimal risk to

study subjects . In exempted 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 considerat ion for the approval of research project under exempted review.

30.6 The Member Secretary shall expedite the review if the proposed research project poses less the minimal risk. The Member Secretary shall also expedite project proposals which was approved and is being re -submitted with some modifications . 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.

30.7 In scheduled IEC meeting , those research project proposals with more than the minimal risk warranted full review will be scrutinized . In such meetings, the decision of two -third members of IEC will be granted approval by the Chairperson. The details of those research project proposals granted exempted and expedited review shall also be presented during the IEC meeting.

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31. Approval of research project proposals

31.1 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.

31.2 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.

31.3 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.

31.4 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 m ade available to the IEC and final approval of research project proposal could be communicated.

31.5 The investigator(s) should also submit the required undertakings on the following for consideration of approval of their project proposal by IEC:

a. Undertaking to follow the national and international guidelines in the implementation of the project.
b. Undertaking to follow Good Clinical Practices.
c. Undertaking to report the progress of their research project every six months and final report after completion of the project.
d. Undertaking to report Serious Adverse Events (SAE) if any.

31.6 The approval of research projects of more than one year duration will be initially awarded approval for a period of one year only. On satisfactory compliance by the investigators in submitting the progress report and documentation, the approval shall be renewed for one more year. The process will be repeated every year till the completion of the project.

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32. Monitoring / Review of approved research projects.

32.1 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.

32.2 Any deviation of protocol or serious adverse event(s) shall be declared, recorded and explanations to be sought to the Principal Investigator.

32.3 The approval of research projects shall be revoked anytime during the course of the research project if it does not conform 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.

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33. Cap on research projects under an investigator

To ensure reasonable contribution and to maintain standards of research practice, any individual investigator (either as principal investigator or as co-investigator) shall not involve in more than 8 projects at a time. This cap on number of research projects on investigators includes their involvement as guide / investigators in PhD, Master level and undergraduate level research projects.

Chapter 5: Policies

34. IEC as DSMB

34.1 The SMIMS IEC would also act as Data and Safety Monitoring Board (DSMB) to monitor and review the conduct of approved research studies.

34.2 For the purpose of DSMB the Member Secretary shall recommend appointment of ad -hoc members of relevant expertise to be on board for effective review of the data and ensure safety of the research study subjects.

34.3 The IEC in the role of DSMB shall critically monitor and review the reported Serious Adverse Events (SAE) to ensure the safety of recruit ed study subjects.

34.4 SMIMS IEC is empowered to visit the place of subject recruitment / intervention and demand / review the collected data on the ongoing research studies and/or seek explanation from the investigator(s) in the event of deviation of resear ch proposal protocol (if any).

34.5 In the event of deviation of research proposal protocol, IEC in the role of DSMB shall revoke the approval and the communication will be sent to the funding agency and licensing authority for necessary a ction.

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35. Studies on special and vulnerable populations

35.1 The special and vulnerable population includes economically or socially /ra cially marginalized population ; mentally challenged population ; Women, Children and Eld erly; Institutionalized population; Refugees; Students; Prisoners ; Surviving victims of natural disasters .

35.2 Studies on students / children:

a. If the students / children (below 18 years) are recruited for the study, then necessary approval should be sought fr om the Principal, Head of the Institution besides approval from parents of the student to be included in the study.
b. For research studies involving the students over and above 18 years, the student should provide explicit consent for participation in the research study.

35.3 For research studies involving the institutionalized elderly, women, children, necessary approval sh ould be taken from the head of

the institutionalized care setting besides approval from the legal guardian of such subjects.

35.4 Academic research on health professional education projects on students:

a. It should not be presumed that an academic project does not fall under the domain of IEC review.
b. Academic projects involving educational interventions on students should also be registered with IEC for approval.
c. If the IEC is satisfied that the students are not coerced or that it would not bring any potential harm to the student – physically, mentally, emotionally or otherwise (influence the academic performance of their regular course of study), the IEC would grant approval for such projects.

35.5 In the event of research studies conducted on such special and vulnerable population the investigator(s) should satisfy IEC that

a. the similar type of research study could not be conducted in the general population for reasons of scientific validity.
b. the outcomes of such research studies are not beneficial to the general population at the cost of potential risk/harm or no benefits to the researched vulnerable population.
c. such research studies would help in furthering the knowledge of disease condition(s) prevalent and/or address health needs in such population.
d. such research studies would provide at the least some direct therapeutic benefits to the participating individuals.

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36. Documentation of Informed Consent
(Abridged from ICMR ethical guidelines 2008)

36.1 All types of research studies (be it clinical or academic) should ensure study subjects' autonomy of voluntary participation in the proposed research study by documentation of informed consent.

36.2 If the study subject is minor or not capable of giving voluntary consent then necessary consent should be taken from the legal guardian of the study subject.

36.3 The Informed Consent Form (ICF) should be presented in an unambiguous language to the study subject. The ICF should have two main components: Information sheet and Consent Form. A copy of information sheet should be made available to study subject participant.

36.4 The information sheet should clearly state the following:

a. Nature and purpose of study stating it as research.

b. Duration of participation with number of participants .
c. Procedures to be followed.
d. Investigations, if any, to be performed .
e. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk .
f. Benefits to participant, community or medical profession as may be applicable .
g. Policy on compensation .
h. Availability of medical treatment for such injuries or risk management .
i. Alternative treatments if available .
j. Steps taken for ensuring confidentiality .
k. No loss of ben efits on withdrawal.
l. Benefit sharing in the event of commercialization .
m. Contact details of Principal Investigator (PI) or loc al PI/Co -PI in multi- centric studies for asking more information related to the research or in case of injury .
n. Contact details of C hairman of the IEC for appeal against violation of rights .
o. Voluntary participation .
p. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines .
q. Storage period of biological sample and related dat a with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results .

36.5 The consent form should clearly state the following
a. The name, age, sex of the study subject.
b. The name, age, sex, relationship with the study subject of the legal guardian (if the study subject is minor).
c. The date on which consent is taken.
d. The method by which consent is documented (read clause 35.6 below).
e. The name, designation of the research project staff documenting the consent.
f. The n ame, designation of the unrelated legal witness (if the study subject gives thumb impression or verbal consent) .
g. The name, designation of the c aretaker, authority of loc al bodies and government agencies in case of study on special and vulnerable population .
h. That the subject / legal guardian understood the implications of participation, risks & benefits associated with the study and his/her participation is entirely on voluntary will and shall withdraw from the study at his/her discretion during the course of research study.

36.6 Methods of consent documentation:

a. All research studies must ensure written consent from the study subject either by means of signature or thumb impression. The identity and signature of the study subject should be verified by the Principal Investigator with any of the following documents v iz. Aadhar Card; Pan Card; Driving License ; Passport; Ration Card or Voter ID Card. The verification should be certified by the PI in the consent form.
b. If the study subject gives thumb impression as a means of consent, then an unrelated legal (over and abo ve 18 years) witness should sign or provided thumb impression along with the study subject.
c. In instances where the study subject declines or could not give signature or thumb impression, verbal consent is acceptable. However such verbal consent should be counter verified with the signature or thumb impression of unrelated legal witness.
d. The consent of the study subject could also be documented in audio -visual form; however utmost confidentiality on subjects' identity should be maintained.

36.7 Need for Fresh a nd/or Re -consent:

a. If there is deviation of intervention protocol against the proposed, then re -consent is to be sought.
b. If there is extension of study period and/or intervention protocol beyond the duration proposed, then re -consent is to be sought.
c. If the study subject attains the legal age (over and above 18 years), regains consciousness or the ability to express voluntary participation then fresh consent should be sought against the consent of the legal guardian or legal unrelated witness.
d. If any of the terms of reference(s) in the information sheet is/are deviated and/or amended.

36.8 Waiver of c onsent:

The documentation of informed consent can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then IECs may waive off the requir ement for informed consent in following instances:

a. When it is impractical to conduct research since confidentiality of personally identifiable information has to

be maintained throughout research as may be required by the sensitivity of the research objective, *eg.* , study on disease burden of HIV/AIDS.

b. Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third -party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
c. Research on blinded biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data f rom repositories or registries etc .
d. In emergency situations when no surrogates ' c onsent c an be taken.

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37. Monitoring of Conflict of Interest.

37.1 A set of conditions in which professional judg ment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non -financial (personal, academic or political) or financial gain is referred as Conflict of I nterest (COI).

37.2 The investigator(s) must declare that there is no potential conflict of interest in undertaking the research study that would subdue the interest(s) of study subject(s) or scientific validity of the research study.

37.3 The investigator(s) mus t declare that they would inform and/or withdraw from the research study if an unforeseen conflict of interest arises amongst the stakeholders of the ongoing research study.

37.4 The investigator(s) must declare that they would distance from the business inter est(s) of the sponsor(s) (pharma ceutic al companies or commercial enterprises) in claiming ownership of developing a new product, patents, copyright or loyalties with vested financial interests.

37.5 The purported conflict of interest against the investigator(s) shall be duly scrutinized by the IEC on a case -to-c ase basis and necessary action be initiated as deemed appropriate. In such instances, the IEC shall revoke the approval of research study and shall report to the sponsor and/or licensing authority for ne cessary a ction.

38. Reporting and Review of Serious Adverse Events (SAE)

38.1 The Serious Adverse Events are those expected and/or unexpected reversible and/or irreversible harm or injury to the study subjects during the course of research study. It is the primary responsibility of the Principal Investigator to explicitly report to the IEC any expected and/or unexpected SAE(s) at the beginning or during the course of research study.

38.2 All SAE's reported to IEC shall be duly reported to the licensing authority, sponsor and the registry.

38.3 The IEC shall also critically review the SAE(s) on study subject(s) reported by subject(s) themselves, legal guardian, sponsor(s) or whistleblowers.

38.4 In the event of expected SAE, the investigator(s) and/or the sponsor(s) should *a priori* stipulate the compensation equitable to the potential event. To this effect such compensation policy should be documented at the beginning of the study; however it may not be explicitly stated in ICF.

38.5 In the event of an unexpected SAE, the investigator(s) and/or the sponsor(s) in discussion and concurrence of the study subject(s) shall decide upon the quantum of compensation equitable to the nature and severity of the event. In the event of disagreement between the study subject and the research team on the quantum of compensation, IEC shall intervene and arbitrate the settlement of due compensation. If still disagreements exist, IEC shall refer the case to the licensing authority or for the legal recourse.

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39. Specific policies on specific research study

39.1 The specific policies on the conduct of different types of research study viz. the clinical evaluation of Drugs, Devices, Diagnostics, Vaccines, Herbal Remedies ; epidemiological studies; human genetics & genomic research; transplantation of organs; assisted reproductive technologies or any other studies, is that the investigator(s) must follow the statutory laws and guidelines prescribed by the licensing authority at the national level; in the absence or deficient guidelines at national level the investigator(s) should adhere to the international policies and guidelines in the conduct of research study.

39.2 To this effect the investigators must follow the current and updated rules and regulations, amended laws prescribing conduct of research study specific to those research areas.

39.3 The investigator(s), IEC members and/or the ad -hoc members shall be assisted by the Office of the IEC in providing the required national/international guidelines, acts and laws in preparing/for review of research project proposals on specific research area s.

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40. Training programs

40.1 The training programs of IEC shall be focused, formal and structured sessions for capacity building and updating of IEC members on ethical issues in research and clinical practice; sensitizing the health sciences faculty on ethical issues during the c onduct of research study; fa cilitate the health sciences fa culty and students to undertake research studies; facilitate the writing skills for publica tion in journals, books, grant writing.

40.2 The Member Secretary shall prepare the calendar of training programs for IEC members, faculty and students and notify the details of such training programs in the annual report or the news letter of the institution.

40.3 There shall be regular training programs organized for each quarter of the calendar year that addresses the objectives of the training program envisaged in the section 39.1 detailed above.

40.4 The Member Secretary shall also incorporate different modes of training through on -line programs or interactive forums for continuous dissemination of ethics related discussion/issues amongst faculty/students.

40.5 The IEC through Dean – Sikkim Manipal Institute of Medical Sciences would compulsorily mandate all post gradu ates undertaking research studies for dissertation to complete a training program during their course of study as part of credit requirement and/or eligibility to make them appear for qualifying exam.

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41. Publications Review

All the publications of health sciences faculty will be subjected to review by IEC for authentication of credit points or incentives as part of fa culty development program. The specific policies of publication review will be notified later.

Chapter 6: SMIMS Research Project Registry

42. Development and Maintenance of Registry

42.1 The IEC in collaboration with the Information and Technology division of Sikkim Manipal University (SMU -IT) shall develop and maintain the SMIMS Research Project Registry.

42.2 The registry shall serve as the webpage of Research Unit of SMIMS as well as of Institutional Ethics Committee.

42.3 The contents of the registry shall be owned by the Member Secretary of SMIMS IEC. The contents of the registry shall include:

a. Organization of SMIMS IEC.
b. Constitution of SMIMS IEC.
c. The past and the standing SMIMS IEC.
d. Download section – SMIMS IEC review application, forms & documents to be attached with the application, SMIMS IEC Standard Operating Procedure.
e. 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 t he proposal to be reviewed.
    v) Other related documents.
f. List of research project proposals reviewed

43. Scope of IEC Registry

43.1 For ensuring transparency of IEC functioning to the stakeholders: The registry shall contain all relevant information on the constitution and functioning of IEC so as to ensure transparency of its functioning to the licensing authority and other stakeholders.

43.2 On-line training programs:
To ensure the continued efforts of IEC in achieving its mandates, the registry shall host on -line training programs / modules for IEC members, health sciences faculty and students.

Secretary shall decide the type of review category viz. Exempted, Expedited or Full Review. The communication on decision of IEC on research project proposals falling under exempted and expedited category shall be processed entirely online; however the res earch project proposals having more than the minimal risk to study subjects as evaluated by the IEC members will be subjected to full review in the convened meetings of IEC.

44. Access rights to IEC registry / website	44.1 The link to the IEC registry / website shall be made available in University website 44.2 The Member Secretary shall be the administrator of the IEC registry / website and shall have exclusive access to all the contents of the registry. 44.3 Other IEC members, ad -hoc members, faculty and students should register with specific username and password to gain access to the contents of the registry / website; however such access shall be prescribed / limited by th e Member Secretary based on specific criterion of the users .