RESEARCH POLICY

SWAMI VIVEKANAND SUBHARTI UNIVERSITY

I. Vision

To be an excellent research university by conducting world-class basic and applied research, scholarship, and creative activities that develops knowledge and contribute to the economic growth and social advancement of nation and benefit humanity as a whole.

II. Mission

To develop and expand innovative research programs and research personnel that align well with institutional mission and strategic plan, address important national and global needs, and through technology transfer, commercialization , human resource development and act as a catalyst for economic and social development of state and the nation.

III. University Research Council/Committee

A. **Chairperson,** Research Council/Committee (Nominee of VC)

B. **Deputy Dean** Research

C. **Deans of Faculties** of University

C.1. Deans will be assisted by Faculty**/Institutional Research Committees/Councils**:

C.1.1.In each Faculty (Institution) there will be an Institutional/(Faculty) research committee

C.1.2.Each Faculty (Institution) will also have Institutional Ethics Committee (where applicable)

C.1.3.In each department there shall be a department research committee.

List of Dean Research from various Faculties (Dean or his nominee)

1 Dean Research Arts & Social Sciences

2 Dean Research Dental Sciences

3 Dean Research Educations

4 Engineering & Technology

5 Dean Research Journalism & Mass Communication

6 Dean Research Law

7 Dean Research Management & Commerce

8 Dean Research Medicine

9 Dean Research Para-Medical Sciences

10 Dean Research Pharmacy

11 Dean Research Science

12 Dean Research Nursing

13 Dean Research Fine Arts

D. Structure and functions of Institution/Faculty Research Committee

1. Each faculty (eg. Medicine/Dental/Engineering etc.) will have a planning officer/coordinator/ Central Research unit(where needed)/finance officer as per needs of that institution and will be headed by Dean(Principal)of the faculty/institution or nominee appointed by him.

2. Dean (Principal) will appoint Coordinator/ planning officer/unit/ of particular faculty, who in turn will report to Dean.

3. Head of concerned department will report to Dean/Principal/ or his nominee (Coordinator) .

4. Principal investigators and Co-investigators will report to their Head of Departments or to Dean or his nominee.

5. Other divisions like compliance committee, internal audit committee, finance and complaint cell will be headed by their respective? Heads in consultation with Dean (Principal) or his nominee who will look after the functioning of their/that departments.

Broad objectives of the University Research Council/Committee:

1. To make and regularly update Research Policy for the University and formulate guidelines to carry out various objectives of the Research Council

2. To consolidate information on faculty Research projects funded by the University under various schemes

3. To consolidate information on Research funded by sources outside the University.

4. To provide overall guidance to Ph.D./M.Phil. Programmes and ordinance related to it

5. To administer various grants and fellowships under schemes accepted by the University

6. To explore funding sources in India and abroad and create linkages as desirable, correlated with the activities of Dean International

7. To generate an overall Research Profile of the University, and periodically review the output, identify gap areas and examine means of supporting research in deserving cases and emerging areas

8. To support undergraduate research and facilitate travel grant to faculty in colleges

9. To grant academic approval to National and International Conferences by University Departments

10. To facilitate activities related to Intellectual Property Rights

11. Foreign Travel for College teachers

12. Conference Applications

13. National /International MoUs

IV. Scope:

a. Research that is part of requirement of award of a degree/diploma
b. Research that is not part of degree curriculum/syllabus
c. Research in collaboration with funding/outside/governmental agencies
d. University/Departments initiated Research

V. Regulations in relations to Research:

As applicable by respective statutory bodies (like Medical Council of India, Dental Council of India, Indian Nursing Council, All India Council of Technical education, Pharmacy Council of India, Department of Science & Technology, Bar Council of India and Regulations, Radiation Protection norms of BARC, Biosafety Committee norms of Department of Biotechnology etc.) and specific laws as applicable at that time. It will be responsibility of Principle Investigators (PI) to comply with all contemporary regulations applicable to research project initiated by him.

INSTITUTIONAL/(FACULTY) RESEARCH COMMITTEES:

Each faculty/institution will have an institutional research committee.

1. Each faculty /Institution will have a research committee headed by Dean or a Chairperson appointed by him. To meet special requirements of subject the Dean will include interdisciplinary resource persons in the committee. There will be provision of finance officer/ and a planning officer/coordinator/unit as per needs of research activity of the faculty. The number of institutional research committee will be 5 or more. Resource persons from outside institution/faculty will be included as needed.

2. Dean(Principal) will appoint Coordinator and and/or Planning officer (research); Central Research unit if needed; interdepartmental broad based statistical team. The coordinator/Planning officer (Research) in turn will report to Dean.

3. The committee will meet once a month or earlier as per needs to deliberate various ongoing Research Activities in the faculty/institution.
4. To stimulate and encourage ideas for encouraging future research projects
5. Evaluate the Research Proposals
6. Guide and encourage faculty members to conduct research in their departments, getting funds, screen presentations /publications sent to conferences/journals and help by reviewing and providing constructive criticism to improve the quality of work.
7. Ensure that requirements as per regulatory guidelines applicable to the project have been fulfilled.

DEPARTMENTAL RESEARCH COMMITTEES

(1) Head of department
(2) One Professor or a nominee of Dean/Principal
(3) Professors in the Department subject to a maximum of four by rotation according to seniority;
(4) Associate Professor/Readers in the Department by rotation according to seniority;
(5) Assistant Professor/Lecturers in the Department qualified to be Supervisor(s) by rotation according to seniority;
(6) Any other professional relevant for the project as decided by head or dean.

Functions of Departmental Research Committee:

Ensuring that the post-graduation student has acquired skills needed for his project.

Peer review and guidance for Postgraduate/Doctoral research projects.

Provide suggestions to research project that are not part of degree of a candidate.

Ensuring the research has complied with university and regulatory guidelines applicable to his research project.

Responsibilities of Research Students

1. Getting up to date information about the topic of his research.
2. Acquiring skills required for his work with the help of supervisor.
3. Preparing thesis/project plan as per norms and in prescribed time
4. Comply with regulatory and legal requirements related with his project
5. Update and coordinate supervisors of the progress of work.
6. Complete the project in time
7. Obtaining Peer review and supervisory comments

Responsibilities of Supervisors:

1. Providing information for clarification of doubts of the candidate regarding the research work.
2. Monitoring and helping the student fulfill his research project responsibilities.
3. Ensure that regulatory and legal guidelines are being followed at all levels of project
4. Ensure compliance of university and institutional guidelines
5. Monitor for plagiarism and ensure student has done his own work
6. Conduct supervisory meetings and being accessible for guidance, meeting with time lines in relation to university requirements, encourage & guide in preparing drafts, peer review, preparation of oral presentation
7. Guiding student to present his work for doctoral committee/oral viva/presentations at conferences.
8. Timely submission of thesis/.research project
9. Notifying head of department or university if they have any concerns about quality or integrity of work

Format of Research Project:

The format of research project will be prepared by individual faculty/institution in accordance with concerned affiliating/regulatory guidelines of council/boards. Deans of different faculties will revise the guidelines as per amendments from time to time and get it notified by the university research committee/council and appropriate authority of university. In case there are special regulations applicable to a department/faculty the same will be got notified by the Dean Academics.

Evaluation and monitoring of performance –

(a) The Dean Research will monitor the performance of faculties/institutions on the basis of agreed criteria and will advise the pro VC/VC on the outcome of the process

(b) The research performance of individual staff is monitored and evaluated by their head of the school, Director or PVC as part of the staff performance development and career planning (PDCP) process.

(c) Staff is required to participate in the external assessment of the performance such as the performance based research fund as directed by their PVC

(D) Staff are required to supply full and accurate details of their research outputs (according to the output types and criteria in appendix B) on an annual basis to their head of the school who will supply the information to the research office.

Human Resource Development in Research

Recruitment policy of new academic staff must give appropriate consideration to the quality of their research record or research potential commensurate with the requirements of the position. Head of institution/Dean/Principal will ensure that new appointments will improve research capabilities of the institution.

Guidelines for intellectual property protection, its licensing and collaborative research with Industry participation

(These guidelines do not constitute legal advice. For help with a particular legal problem, advice from an intellectual property lawyer may be sought)

Guidelines for intellectual property protection and its licensing

1. An IPR facilitating cell, an interface between the SU faculty and the Patent/copyright attorney shall guide and help the faculty and students of Subharti University in patentability assessment and to apply for patents / copyright/ trademark applications.

2. The University faculty desirous of filing a patent or copyright or trademark application would be t advised to contact the IP cell regarding these issues.

3. An internal approval form (available at IP cell) filled by the PI wherein names of the inventors/authors shall be mentioned, is to be signed by the PI and forwarded by the HOD for approval of the Dean Research of the respective subject with recommendation of the IPR Chair.

4. Invention disclosure description (in invention disclosure format) is to be forwarded along with the duly signed approval form to the IP cell for further action.

5. Invention disclosure/ Patent/Copyright/Trademark and similar documents are to be treated as confidential and would be placed under special duty to maintain confidentiality by the signing of a Non-Disclosure Agreement by personnel of the IPR cell.

6. Since patenting is expensive, efforts should be made to get the patent filed through other funding agencies such as DBT, NRDC and DST (TIFAC).

7. The IP cell shall help the inventor in drafting of the patent specification / copyright or trademark application and filling of relevant forms.

8. The draft application along with the relevant forms shall then be forwarded to a patent attorney present on the panel of University.

9. The IPR cell shall correspond with the attorney and the inventors on IP matters.

10. The committee for approval for patent filing would consist of: Concerned HOD, Dean Research of the subject, the IP Chair and Finance Officer or his nominee in casewhere SU funds need to be utilized.

11. The inventors would be required to cooperate with the IP cell to expedite furnishing of information for timely actions since delay would mean payment of extra fee to the patent office and the attorney.

12. Any work sought to be filed by a faculty member and or students arising out of R&D work done at the University will required to be filed in joint names as inventors or authors while University shall be to the owner of IP.

13. After filing of the application for IP protection, the inventors shall inform the IPR cell of any further development, if any, in the related R&D work.

14. The IPR Cell and inventors in collaboration with Research Council shall work together for dissemination of the Intellectual property to public and industry to aid in commercialization.

Guidelines for collaborative research with Industry participation

The Collaborative R&D Projects constitute the projects wherein there are two or more agencies are the participants. These projects are partially funded by a private entity (client) and/or supplemented by the university and/or by a Government R&D funding agency. These projects can be for up scaling & validation of lab level knowhow or for technology development.

To smoothen the process of collaborative R&D with Industry and tech transfer, robust and broad guidelines are required to be formulated by the University for:

a. Project costing/costing of technology/know-how,
b. Permissions required by the PI for collaborative research with industry and tech transfer and authorized signatories for the same,
c. Modalities of IP protection and its maintenance,
d. Source of the funds required for IP protection and maintenance,
e. Modalities of IP protection (whom to approach, authorized department/officer/committee),
f. The terms and conditions of MOA for collaborative R&D and authorized signatories,
g. Evaluation of technology/know-how.
h. Ownership of the patents, if any, generated out of the collaborative research
i. Modalities of tech transfer/IP licensing from identification of private partner,negotiations, MoA finalization to finalization of terms and conditions etc.)

A committee must be constituted for approval of Technology Transfer. It may consist of the inventor, The Head of the respective Department, Dean Research of the concerned subject,Dean of the faculty and the IPR Chair.

Salient features of the terms and conditions for the collaborative R&D projects to be built up in the Memorandum of Agreement for collaborative R&D IPR Issues

1. Non-disclosure agreement may be signed with the private party prior to discussions

and negotiations.

2. The responsibilities and deliverables expected from all the participating agencies should be clearly mentioned in the MoA for collaborative work.

3. Back ground Knowledge: The background knowledge is the know-how already developed by the university which is to be either further developed or validated by the company on implementation of the collaborative project. The background knowledge document/s is to be clearly mentioned in the MoA and appended as an annexure.

4. The exit and arbitration clauses for all the participating agencies should be well formulated in the MoA so as to avoid future legal disputes in case of premature project closure.

5. The IP rights for the IP generated out of the collaborative project shall be jointly shared among the participating agencies.

6. The intellectual property, product, prototype or process generated out of such projects shall be co-owned among the participants on mutually decided terms.

7. Costs of IP protection and its maintenance to be equally shared among the participating agencies.

Terms and conditions to be taken care of for licensing of the know-how developed from the collaborative work

i. The private party (company) shall have first right to license and commercialize the developed know-how and resulting IP, if any.

ii. In case the company is not interested to license the IP/know-how developed, the university and the Government agency (funding body) shall be free to license and transfer the know how to another suitable party.

iii. The non-exclusive technology transfer should be preferred but in case the private party insists, technology may be transferred on exclusive basis at a higher rate for fixed time duration.

iv. Liability/Indemnity: The licensee shall indemnify Subharti University (Licensor) against any harm or suit brought about by the third party relating to technical knowhow or the products developed by the Licensee.

v. Any liability to the licensor in connection with licensed know-how/IP* shall be up to a ceiling of the sum received from the client.

(* These refer to special conditions such as failure of licensed know how and/or false claims for the licensed knowhow).

vi. The cost of the developed know how is to be calculated based on direct expenses, intellectual fee and service tax etc. incurred by the University. Direct expenses comprise manpower costs, cost of consumables & chemicals, infrastructural services, equipment usage cost and contingencies.

vii. Intellectual fee would comprise a percentage (in a range of 30-50%) of total expenses incurred by the university and would also include a component of patent protection & maintenance costs per country where the company wishes to commercialize the know-how. The patent charges to be decided on mutual negotiations and agreement.

An outline of the protocol for this purpose can be as below:

1) The investigator should be asked to make a presentation to establish before the committee the nature of technology and whether it is ready for transfer.

2) The committee should also discuss the worth of the technology in terms of royalties etc. (maximum and minimum) before putting the advertisement.

3) Subsequently, Advertisement can be put on the SU website to call for letter of interest. The advertisement should have link to details of technology, minimum value asked for etc.

4) Once the letter of Interest are received by the PI or University authorities, the interested companies can be asked to present their strengths in commercializing the technology before the translational committee.

5) Shortlisting of Companies as per the decision of the committee.

6) Negotiation for upfront amount and royalties.

7) MOA signing and technology transfer

8) Commercial validation by the company

9) Finalization of commercial product

10) Launching of product by company.

Elements of costing of collaborative R&D project with Industry participation

The main components here would be:

1. Direct expenses that comprise manpower costs, cost of consumables & chemicals, infrastructural services, equipment usage cost and contingencies.

2. Intellectual fee can range from 30 to 50 % of total expenses. This cost reflects the intellectual capability developed by the project implementing scientists/technologists.

Details:

(1) Man-day costs: These constitute charges based on the actual time spent on the project (man-days) for the S&T manpower deployed for the project. There would be different costs for different levels of manpower for example Faculty, Research associate, Research/project assistants/ Senior Research fellow, Junior Research Fellows etc. based on actual time spent on the activity

S. No. Category of Staff Man Power rates, Rs.Per day Per year

1. Professor: As per Institution Scales

2. Associate Professor: As per Institution Scales

3. Assistant Professor As per Institution Scales

4. Technician As per Institution Scales

5. Research Associate/ Research Assistant/JRF/SRF Actual salary with 40% overheads

(2) Costs of Chemicals and Consumables: 100% cost plus 20% overheads

(3) Equipment usage costs: these reflect yearly usage charge and can be 20% of the cost of equipment (in case of old equipment, depreciation at the rate of 20% per annum may be taken).

(4) Contingencies: Any unforeseen expenditure required for implementing the project (travel, stationary, other research expenses such as photography work, sundry small purchases etc.).

(5) Intellectual fee: Intellectual fee comprises efforts and expenses incurred over a period of time for capacity and expertise build up.

Animal Experimentation:

All animal experiments will be conducted in compliance of CPSCEA, Govt. of India, guidelines and only after approval of IAEC (Institutional Animal Ethics Committee) as per provisions of law.The objective of the operating procedure (Ministry of Environment & forests, Govt. of India) is to contribute to the effective functioning of the Institutional Animal Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation Rules 1998.

CPCSEA Standard Operating Procedures (SOP) for IAEC

1. Objective:

The motto of Prevention of Cruelty to Animals (PCA) Act 1960 as amended in1982, is to prevent infliction of unnecessary pain or suffering on animals. The Central Government has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. For this purpose, the Government has made "Breeding of and Experiments on Animals

(Control and Supervision) Rules, 1998" as amended during 2001 and 2006, to regulate the experimentation on animals.The objective of this SOP is to contribute to the effective functioning of the Institutional Animal Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation Rules 1998..

IAEC has been designed to secure the following objectives:

(a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;

(b) that experiments are performed with due care and humanity and that as far aspossible experiments involving operations are performed under the influence of some anesthetic of sufficient power to prevent the animals feeling pain;

(c) that animals which, in the course of experiments under the influence of anesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;

(d) that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;

(e) that experiments on larger animals are avoided when it is possible to achieve thesame results by experiments upon small laboratory animals like guinea-'pigs,rabbits, mice, rats etc;

(f) that, as far as possible, experiments are not performed merely for the purpose ofacquiring manual skill;

(g) that animals intended for the performance of experiments are properly looked afterboth before and after experiments;

(h) that suitable records are maintained with respect to experiments performed onanimals

2. Functions of IAEC

As defined in “Breeding of and Experiments on Animals (Control andSupervision) Rules, 1998”

"Institutional Animals Ethics Committee" means a body comprising of agroup of persons recognized and registered by the Committee for the purpose ofcontrol and supervision of experiments on animals performed in an establishmentwhich is constituted and operated in accordance with procedures specified for thepurpose by the Committee;

The primary duty of IAEC is to work for achievement of the objectives asmentioned above.

IAEC will review and approve all types of research proposals involving smallanimal experimentation before the start of the study. For experimentation on largeanimals, the case is required to be forwarded to CPCSEA in prescribed manner withrecommendation of IAEC.

IAEC is required to monitor the research throughout the study and aftercompletion of study through periodic reports and visit to animal house and laboratorywhere the experiments are conducted. The committee has to ensure compliance withall regulatory requirements, applicable rules, guidelines and laws.

3. Composition of IAEC

Institutional Animals Ethics committee shall include eight members as follows.

1. A biological scientist,

2. Two scientists from different biological disciplines,

3. A veterinarian involved in the care of animal,

4. Scientist in charge of animals facility of the establishment concerned,

5. A scientist from, outside the institute,

6. A non scientific socially aware member and

7. A nominee of CPCSEA

Specialist may be co-opted while reviewing special project using hazardousagents such as radio-active substance and deadly micro organisms.

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from amongst the eight members. Members againstSerial number 5,6 and 7 will be nominated by CPCSEA, with a provision of a Linknominee for CPCSEA nominee.

4. Authority under which IAEC is constituted and duration:

CPCSEA constitutes the IAEC on receipt of five (5) names against serialnumbers 1-4 from the institute. The duration of IAEC is for a period of 3 years and isrequired to be reconstituted at the time of renewal of registration. However, changesmay be made in deserving cases with the approval of CPCSEA.

5. IAEC requirements:

a. The duration of appointment is for a period of 3 years (coterminous withregistration).

b. The committee is required to be reconstituted at the time of renewal ofregistration, and at least half of the members will be replaced.

c. A member can be replaced in the event of death or long-term non-availabilityor for any action not commensurate with the responsibilities laid down in theguidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons todo so.

e. All members should maintain absolute confidentiality of all discussions duringthe meeting and sign a confidentiality form.

f. Conflict of interest should be declared by members of the IAEC.

g. IAEC is required to formulate a SOP for its working requirements and followit in all the meetings.

6. Quorum requirements:

The minimum of 6 members are required to compose a quorum. All decisionsshould be taken in meetings and not by circulation of project proposals. Presence ofCPCSEA nominee is a must. Link nominee can attend in case main nominee conveyshis unavailability in writing to the Chairman IAEC. Socially aware member'spresence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year.

7. Conduct of business:

The Chairperson will conduct all meetings of the IAEC. If for reasons beyond control, the Chairperson is not available, or has conflict of interest an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

8. Participation by Investigators / experts in IAEC.

IAEC may call upon subject experts who may provide special review ofselected research protocols, if need be. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IAEC. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

9. Application Procedures:

a. All proposals should be submitted in the prescribed application form, thedetails of which are given under Documentation.

b. All relevant documents with checklist should be enclosed with application form

c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI)and Co-investigators / Collaborators should be submitted to IAEC.

11. Review procedures:

a. The meeting of the IAEC should be held on scheduled intervals as prescribedin the concerned SOP of the IAEC and additional meetings may be held ifthere are reasons to do expedited review.

b. The proposals will be sent to members at least 15 days in advance.

c. Decisions will be taken by consensus after discussions. Negative view pointsshould be recorded in the minutes. In case consensus is not reached, the caseshould be referred to CPCSEA.

d. Researchers will be invited to offer clarifications if need be.

e. Independent consultants/Experts will be invited to offer their opinion onspecific

Research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writingwith signature of all the IAEC members present.

14. Decision-making

a. Members will discuss the various issues before arriving at a consensusdecision.

b. A member should withdraw from the meeting during the decision procedureconcerning an application where a conflict of interest arises and this should beindicated to the chairperson prior to the review of the application and recordedin the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d. Only members can make the decision. The experts / investigators / inviteeswill only offer their opinions.

e. Decision may be to approve, reject or revise the proposals. Specificsuggestions for modifications and reasons for rejection should be given.

f. In cases of conditional decisions, clear suggestions for revision and theprocedure for having the application re-reviewed should be specified.

g. Modified proposals may be reviewed by an expedited review throughidentified members.

h. Procedures for appeal by the researchers should be clearly defined**.**

15. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.

b. Suggestions for modifications, if any, should be sent by IAEC.

c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by the IAEC should be communicatedto the PI.

16. Follow up procedures

a. Reports should be submitted at prescribed intervals for review.

b. Final report should be submitted at the end of study.

c. All Serious Adverse Events (SAE's) and the interventions undertaken shouldbe intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted to IAEC for renewedapproval.

f. Any new information related to the study should be communicated

g. Premature termination of study should be notified with reasons along withsummary of the data obtained so far.

h. Change of investigators / sites should be informed and approval of IAECshould be taken.

17. Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of IAEC including training programsin animal ethics attended.

b. Copy of all study protocols with enclosed documents, progress reports.

c. Minutes of all meetings duly signed by the Chairperson and the members.

d. Copy of all existing relevant national and international guidelines on animalethics and laws along with amendments.

e. Copy of all correspondence with members, researchers and other regulatorybodies.

f. Final report of the approved projects.

g. Record of Breeding of animals, supply etc, if breeding of animals isundertaken.

h. Record of import of animals with species, source, quantity, usage etc.

i. Record of all Contract research, if conducted at the institute.

j. Record of rehabilitation of large animals if done.

k. All documents should be archived for period as prescribed in the concernedSOP of the IAEC. However, this should not be less than one year.

18. Updating IAEC members

a. All relevant new guidelines and amendments to the Rules and Act should bebrought to the attention of the members.

b. Members should be encouraged to attend national and international trainingprograms / workshops / conferences in research ethics for maintaining qualityin ethical review and be aware of the latest developments in this area.

19. Reporting to CPCSEA

a. IAEC is required to send a copy of minutes of IAEC meeting to CPCSEAwithin 15 days.

b. Inspection report of animal house with photographs by IAEC members isrequired to be sent once in a calendar year. If action is required, the facilitymust provide ATR within 30days.

20. Reimbursement to CPCSEA representative

CPCSEA representative(s) on the IAEC or authorized person(s) sent forinspection of the establishment(s) are required to be paid Rs. 1000/- each as sittingfees and reimbursement of actual expenditure incurred in this regard (if not providedby the establishments / organizations).

21. Fees Payable to CPCSEA

Registration fee of Rs. 1,000/- and renewal fee of Rs. 500/- is to be paid byDemand Draft in favor of CPCSEA payable at New Delhi (as applicable).

22. All communications must be addressed to:

Member Secretary, CPCSEA,Ministry of Environment & Forests,8th floor, Jeevan Prakash Building, 25, Kasturba Gandhi Marg,New Delhi-110 001. Phone : 011-23318553.Email : cpcsea@rediffmail.com

RESEARCH IN HUMANS: INSTITUTIONAL ETHICS COMMITTEE

All human research projects are to be done only after obtaining approval from Institution al Ethics Committee that is formed as per Regulations of ICMR & Drugs & Cosmetics Act

Institutional Ethics Committee

The Institutional Ethics Committee is constituted by the authority & responsibilities vested in the Principal, Subharti Medical College by the regulations of Medical Council of India
The Institutional Ethics Committee will function in accordance with guidelines laid down by Indian Council of Medical Research and Schedule Y of Drug & Cosmetic Rules.

.

Introduction
It is mandatory that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC). It has to ensure a competent review of all ethical aspects of the research proposals and advice the researchers on all aspects of the welfare and safety of the research participants.
Standard Operation Procedure of Ethical Committee is made with aims & objectives of:

1. **Purpose:**
   - Describe the guidelines to start research
   - Provide modalities (operative procedures) for the members of Institutional Ethical committee to scrutinize the research proposals

2. **Scope:**
   The SOP will be applicable to all bio-medical researches including epidemiological studies, clinical trials of drugs/vaccines/diagnostics etc and genetics & genomic research.

3. **Responsibilities:**

- To safeguard the rights, safety and wellbeing of all human participants.
- Review the proposed research project within a reasonable time, preferably within 3 months, and document its views in writing, clearly indicating:
  - Approval/favorable opinion;
  - Modifications required prior to its approval/favorable opinion;
  - Disapproval/negative opinion; and
  - Termination/suspension of any prior approved/favorable opinion.
- IEC will conduct continuing review of each ongoing trial first at 6 months and then at regular intervals, at least once a year.
- IEC will also review old researches on the issues of result and short falls etc.
- When a non-therapeutic trial is to be carried out with the consent of the subject or his legally acceptable representative, IEC will determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
- Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible as in emergency situations, IEC must ensure that proper steps are taken in the proposed protocol and/or other documents (s) to meet out regulatory/ethical requirements for such trial.
- In case of injury or illness during trial IEC will ensue that information regarding compensation/payment to subjects, including the methods, amounts, and schedule of payment is properly documented in the protocol and it should be set forth in the written informed consent form or any other written information to be provided to subjects.
- IEC will review both the amount and method of payment to subjects.

4. **Composition of IEC**

IEC iis constituted as per the direction given in Appendix-VIII of schedule-Y of Drugs & Cosmetics Rule. Effort is made to have good representation of experts of different disciplines/ area of specialization in ethics committee.

The composition of IEC is as follows:

1. Chairperson (from outside the institution)
2. Basic Medical Scientist (preferably one pharmacologist).
3. Faculties of the institution/Clinicians (not more than three)
4. One legal expert
5. One social scientist/representative of nongovernmental voluntary agency/philosopher/ ethicist /theologian or similar person
6. One lay person from the community
7. Member-secretary

The members of IEC must have high experience in the area of their specialization. They must be competent enough to understand the pros & cons of the proposed work on human being in general and on society and review the projects independently.

The Member secretary, who generally belongs to the same institution, conducts the proceedings of the Committee. Other members should be a mix of medical/non-medical scientific and non-scientific persons including lay persons to represent the differed points of view:

If required one subject expert could be invited to offer their views on that particular subject.

The members should be appointed by the Principal of the Subharti Medical College Meerut based on their competencies and integrity, and could be drawn from any public or private institute from anywhere in the country.

5. Authority under which IEC is constituted

The Principal, Subharti Medical College Meerut by authority & responsibilities vested in him by the Medical Council of India and in accordance of Drugs & Cosmetic Rules

6. Membership Particulars and conditions of appointment (As per Annexure VIII of Schedule Y)

Qualities sought in IEC members:

- interest and motivation,
- commitment and availability,
- experience ,education and training,
- respect for divergent opinions,
- interest in committee work,
- integrity, and
- diplomacy.

Conditions of appointment

a) Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines and the ICMR code and Drug & Cosmetic Rules.

b) The duration of appointment is initially for a period of three years. The appointment may extend for another term if desired.

c) A member can be replaced in the event of death/transfer /long term non availability / for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d) A member can tender resignation from the committee with proper reasons to do so

e) All members should maintain absolute confidentiality of all discussions during the meeting.

f) Name, age, gender, profession, and affiliation will be publicized whenever the committee is reconstituted or there is a change in the membership.

g) Conflict of interest to be disclosed if any exists.

h) An investigator can be a member of the EC; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest.

7. Quorum requirements

The meeting of IEC will be conducted once in a three months. For a meeting to be valid and the decisions to be binding, there shall be a quorum of 5 members personally present with at-least one non institutional member being present. (Chairperson, One Clinician, One

basic Scientist, One Legal Expert, One Lay person from the community is deemed necessary to fulfill the quorum).

8. Special Invitees

Principal Investigator (PI) or a study team member or any outside expert (independent consultant (s) who may provide special review of selected research protocols, if needed may be in the capacity of being specialists in ethical or legal aspects, specific disease or methodologies or represents specific communities etc to give their specialized views in regard to the matter placed before the EC for consideration and decision) may be invited by the member secretary and be allowed to attend any EC meeting as a special invitee for presenting specific protocols/papers etc. and also clarify and answer any and all queries and doubts of EC members on such protocol etc.

9. Application procedure:

The researcher should submit an application in a prescribed format along with the study protocol. A forwarding letter through proper channel should accompany the submission. Minimum nine (9) copies of the proposal along with the application and documents are to be submitted for consideration in the IEC meeting. The date of meeting will be intimated to the researcher and he has to be present for any clarification. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

The protocol should include most of underlying papers as per requirements of the research proposal:

1. The title with signature of Principal Investigator (PI) and Co-investigators
2. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
3 Recent curriculum vitae of the Investigators indicating qualification and experience
4. Procedure of selection of participant and brochures, if any
5. Inclusion and exclusion criteria for entry of participants.
6. Precise description of methodology including sample size & type of study design
7. Plan to withdraw or withhold standard therapies in the course of research.
8. Plan for statistical analysis of the study.
9. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and local languages.
10. Safety of proposed intervention and any drug or vaccine to be tested
11. For research involving more than minimal risk, an account of management of such risk or injury.
12. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. A corpus fund of Rs. One lakh may instituted in form of security to meet out such expences.
13. An account of storage and maintenance of all data collected during the trial.

14. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
15. A statement on probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control
16. All other relevant documents related to the study protocol like investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.
17. Agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.
18. Details of Funding agency/ Sponsors and fund allocation.
19. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
20. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
21. A statement on conflict-of-interest (COI), if any.

10. Special Considerations

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC as in research involving:

- Children, pregnant and lactating women
- Vulnerable participants and
- Those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration etc.

11. **Review procedures**

Every research proposal on human participants should be reviewed by IEC before the research is initiated.

It should be ensured that a scientific evaluation has been completed before ethical review is taken up. The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and the justice issues.

All the proposals shall be screened by the IEC's member-secretary or secretariat for their completeness & depending on the risk involved and categorizes them into three types:

- Exemption from review
- Expedited review and
- Full review

Minimal risk is one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant

undergoing these interventions since it would be undertaken as part of current everyday life.

11.1.1 Exemption from review

Proposals which present less than minimal risk fall under this categoryas may be seen in following situations:

i. Research on educational practices such as instructional & evaluation strategies or effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Exceptions:

i. When the confidentiality cannot be maintained and the disclosure of information could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

ii. When interviews involve direct approach or access to private papers.

11.1.2 Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review as when:

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Clinical studies of drugs and medical devices only when
    - Research is on already approved drugs or
    - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention.

The Member- Secretary and the Chairperson of the IEC or designated member of the Committee/ Subcommittee of the IEC review such protocol.

11.1.3 Full Review

All research presenting with more than minimal risk or involve vulnerable population and special groups (children, pregnant or lactating mother) shall be subjected to full review by all the members. Whether the review is done by all reviewers or by primary reviewer(s), a brief summary of the project with informed consent and patient information sheet, advertisements or brochures, if any, should be circulated to all the other members.

The ethical review should be done in formal meetings and EC should not take decisions through circulation of proposals.The committee should meet at regular intervals and should not keep a decision pending for more than 6 months. The ongoing research may be

reviewed at regular intervals of six months to one year or when new information or adverse event is reported.

11.2 The following will be considered, as applicable:

11.2.1 Scientific Design and Conduct of the Study

- the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
- the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
- the justification for the use of control arms;
- criteria for prematurely withdrawing research participants;
- criteria for suspending or terminating the research as a whole;
- the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB);
- the adequacy of the site, including the supporting staff, available facilities, and emergency procedures;
- the manner in which the results of the research will be reported and published;

11.2.2 Care and Protection of Research Participants

- the suitability of the investigators' qualifications and experience for the proposed study;
- any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;
- the medical care to be provided to research participants during and after the course of the research;
- the adequacy of medical supervision and psycho-social support for the research participants;
- steps to be taken if research participants voluntarily withdraw during the course of the research;
- the criteria for extended access to, the emergency use of, and/or the compassionate use of study products;
- the arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so;
- a description of any plans to make the study product available to the research participants following the research;
- a description of any financial costs to research participants; the rewards and compensations for research participants (including money, services, and/or gifts);
- the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research;
- the insurance and indemnity arrangements;

11.2.3 Protection of Research Participant Confidentiality

- a description of the persons who will have access to personal data of the research participants, including medical records and biological samples;
- the measures taken to ensure the confidentiality and security of personal information concerning research participants.

11.2.4 Informed Consent Process

- a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent;
- the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s);
- clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals;
- assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being;
- the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

11.2.5 Community Considerations

- the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;
- the steps taken to consult with the concerned communities during the course of designing the research;
- the influence of the community on the consent of individuals;
- proposed community consultation during the course of the research;
- the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs;
- a description of the availability and affordability of any successful study product to the concerned communities following the research;
- the manner in which the results of the research will be made available to the research participants and the concerned communities.

11.2.6 Recruitment of Research Participants

- the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity);
- the means by which initial contact and recruitment is to be conducted;
- the means by which full information is to be conveyed to potential research participants or their representatives;
- inclusion criteria for research participants;
- Exclusion criteria for research participants.

12. Essential documents to be circulated / given to EC members for ethical approval

Whenever the meeting of EC is held to consider and accord its decision on any protocol /trial etc., the Member secretary shall ensure that the PI makes available copies (one for the EC, one each for each member of the EC and one for the institution) of his /her application letter with the copies of the following documents:

a. Protocol in detail and its Amendments (if any)
b. Investigator's brochure and any safety information available and necessary for making considered decision
c. Format of Informed Consent Form and Patient Information Sheet in English and the relevant translated languages and with 'back-translation' certificates
d. Any other project-specific documents: Subject recruitment procedures (i.e. advertisements)

e. Information about financial compensation /benefits to the trial subjects.
f. Current CV of the Principal Investigator.
g. Required Regulatory Clearance form DCGI which shall provide about the specific protocol details and reference number.
h. Approval Letter from DGFT (wherever applicable).
i. Draft of Clinical Trial Agreement (Sponsor – CRO-Institution and Principal Investigator as the case may be)
j. Letter of Undertaking by the Principal Investigator to DCGI
k. Insurance Cover containing the title and reference of the protocol with names of Sponsor / CRO as may be applicable, details of coverage (All medical expenses – investigative, preliminary, treatment, hospitalization and post hospitalization cost (s) to all the participant (s) in this trial form the time they give their informed consent till the completion of the trial. Losses, expenses, legal costs, awards and compensations arising out of any, attributable, related or arising out of the Protocol/Trial, medicines, adverse events etc, caused/incurred and / or to be incurred by all the patients, staff of Sponsor / CRO Institution /PI apart from members of EC), procedure for claim lodging and settlement, validity (at least for some reasonable period apart from the duration of the protocol being covered).
    1. In the event the Insurance cover note does not so specify, there should be an indemnity letter of the Sponsor / CRO undertaking liability for all the coverage specified in para 11 and indemnifying and keeping indemnified all the personnel therein.
    2. The procedure from claim shall be provided as follows:
        a. The emergent, first aid expenses met by the Investigator and the Centre should be immediately paid / reimbursed.
        b. Any claim on the hospital, investigator, medical practitioners, ethics committee etc. by the any patient or his/her legal representative shall be paid by the Sponsor immediately and the sponsor shall take up the claim form insurance company subsequently.
        c. Any exclusions should be specified and be clear, precise and not vague.
        d. Legal redressal through arbitration (as may be needed) should be under Indian legal jurisdiction.

13. **Meeting and the review process**
    a. Ordinarily the IEC will meet once in 3 months. Extraordinary meeting can be called with the consent of the chairperson for discussion of urgent matters.
    b. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerns.
    c. The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the chairperson is not available, and alternate chairperson will be elected from the members by the members present, who will conduct the meeting.
    d. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

e. Researchers will be invited to offer clarifications if need be. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
f. The decisions will be minuted and Member –Secretary will get it approved and signed by the chairperson before communicating to the researchers.

14. Decision Making Process

a. Decisions for review of research proposals will be made only in meetings where quorum is complete. Only members can make the decision. The expert consultants will only offer their opinions.
b. Members will discuss the various issues before arriving at a consensus decision. In the meeting, EC will review new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings. The following points should be considered while doing so:
    1. The decision must be taken by a broad consensus and the Member Secretary should communicate the decision in writing to the PI.
    2. If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting and it should also be recorded in the minutes.
    3. If one of the members has her/his own proposal for review or has any COI then s/he should withdraw from the IEC while the project is being discussed
    4. A negative decision should always be supported by clearly defined reason
    5. An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
    6. The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
    7. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
    8. The following circumstances require the matter to be brought to the attention of IEC:
        a. any amendment to the protocol from the originally approved protocol with proper justification;
        b. serious and unexpected adverse events and remedial steps taken to tackle them;
        c. any new information that may influence the conduct of the study.
    9. If necessary, the applicant/investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or interest groups can be invited during deliberations to offer their viewpoint.
    10. Subject experts may be invited to offer their views, but should not take part in the decision making process. However, her / his opinion must be recorded.
    11. Meetings are to be minuted which should be approved and signed by the Chairperson/ alternate Chairperson/ designated member of the committee.

15. **Minute**

The member secretary shall cause to maintain proper record of the proceedings of each meeting either in a loose leaf form (duly kept under lock and key with all pages numbered,

signed by the Chairman) or in a book. Such minutes shall include the date, time and venue of the meetings, name of members present, details of leave of absence if any accorded, summary of discussions, queries and clarifications and also the decision of the EC on each item and wherever approvals are accorded decision of conditions, if any imposed by the EC. The minutes shall also specify the names with reasons for any member 'abstaining' from voting on account of being an interested member. Minutes will be circulated to the members maximum within two weeks of the date of holding the meeting.

16. Conveying decision/directions of the EC

Any decision/direction and /or instruction of the EC, after duly being minuted and signed by the chairman, shall be conveyed, to any party including the PI, by the Member Secretary or anyone else specifically authorized for such purposes. Suggestions for modifications or reasons for rejection will be included in the decision-letter from the IEC. The schedule / plan of ongoing review by the IEC will be communicated to the PI.

17. Monitoring / Follow up for Ongoing Trials

Once IEC gives a certificate of approval it is the duty of the IEC to monitor the approved studies. IEC will follow-up progress of all studies from the time the decision was taken until the completion or termination of the research study. The follow-up review must be at least once a year.

a. A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the committee's original decision or confirmation that the decision is still valid.
b. In the case of the premature suspension/termination of a study, the applicant must notify the IEC of the reasons for suspension/termination.
c. IEC should receive notification from the applicant at the time of the completion of a study. IEC should receive a copy of the final summary or final report of a study.
d. Any serious Adverse event will have to be reported to Chairperson/ Member Secretary of IEC immediately by telephonic communication and then by a written communication within Seven days.
e. The welfare of the study participant and actions taken to address the SAE should be communicated to the Committee until the study participant is discharged. The Member receiving the communication on the SAE will communicate the same to other Members during subsequent meetings as well as inform them of the action taken by the CRO/ applicant to address the SAE.

18. SERIOUS ADVERSE EVENT REPORTING

When a subject who is participating in a research study experiences an unexpected or serious adverse event, the PI must promptly report the incident to the Data and Safety Monitoring Subcommittee of the IEC. A summary of the adverse event must be submitted to the Data and Safety Monitoring Subcommittee of the IEC. For adverse events or reactions that occur at SMCH the following apply (hospitalization for any reason must be reported):

- If the adverse event or reaction was anticipated in the protocol and the subject was informed about the possibility of the event in the consent form, there is no need to inform the Data and

Safety Monitoring Subcommittee of the IEC unless the adverse event was unexpectedly serious, life threatening, or fatal.

- If the adverse event or reaction was unanticipated, unexpectedly serious, life-threatening or fatal, the adverse event must be reported to the Data and Safety Monitoring Subcommittee of the IEC office within 24 hours. If the adverse event occurs after hours or on a week-end, notification should be sent to the Secretary Data and Safety Monitoring Subcommittee of the IEC.
- If the research study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must then notify the regulatory authorities within 24 hours.
- If the PI holds the Investigational New Drug (IND) or Investigational New Device Exemption (IDE) in his/her name, he/she is required to notify the regulatory authorities of the adverse event or reaction within 24 hours, in addition to notifying the Data and Safety Monitoring Subcommittee of the IEC.
- Notifying the Data and Safety Monitoring Subcommittee of the IEC does not relieve the PI from his/her responsibility to notify the sponsor, regulatory authorities.
- Within 10 working days, the PI must submit a written report of the adverse event or reaction to the Data and Safety Monitoring Subcommittee of the IEC in the specified format.
- For industry sponsored research trials of drugs or devices, sponsors are required to inform investigators of adverse events or reactions that occur at other sites. When PIs are informed of the adverse events in sponsor safety memos and other correspondence, the PI must review the adverse event report and then notify the Data and Safety Monitoring Subcommittee of the IEC. This should be done as promptly as possible after receipt of the report from the sponsor.

19. **Records Keeping and Archiving:**

All documentation and communication of "IEC" will be dated, filed, and preserved for a minimum period of 5 years following the completion or termination of the study (both in hard & soft copies). The following records should be archived for the following:

- The Constitution and composition of the IEC
- Signed and dated copies of the latest the curriculum vitae of all IEC members with records of training if any
- Standing operating procedures of the IEC
- National and International guidelines for submission established by IEC
- Copies of protocols submitted for review
- All correspondence with IEC members and investigators regarding application, decision and follow up
- Agenda of all IEC meetings
- Minutes of all IEC meetings with signature of the Chairperson
- Copies of decisions communicated to the applicants
- Record of all notification issued for premature termination of a study with a summary of the reasons
- Final report of the study including microfilms, CDs and Video recordings.
- The final summary or final report of the study.
- IEC register: The details of protocol like the date of receipt, date of discussion, date of approval, follow up and date of final report are recorded in these registers.

20. **Processing fee**: No fee will be charged for Institution initiated research project, post graduate thesis, ICMR project taken up by students and research projects started by faculty without any funding from outside sponsors.
21. **Amendments**: In view of new amendments in regulations and new situations suitable amendments will be done.
22. **Appeals**

    In case of disapproval, the investigators may appeal in writing to the Chairperson for a repeated review stating sufficient grounds as to why the matter should be reopened. The Chairperson's decision in this will be final.

    This order will come into effect immediately & will be effective until further.