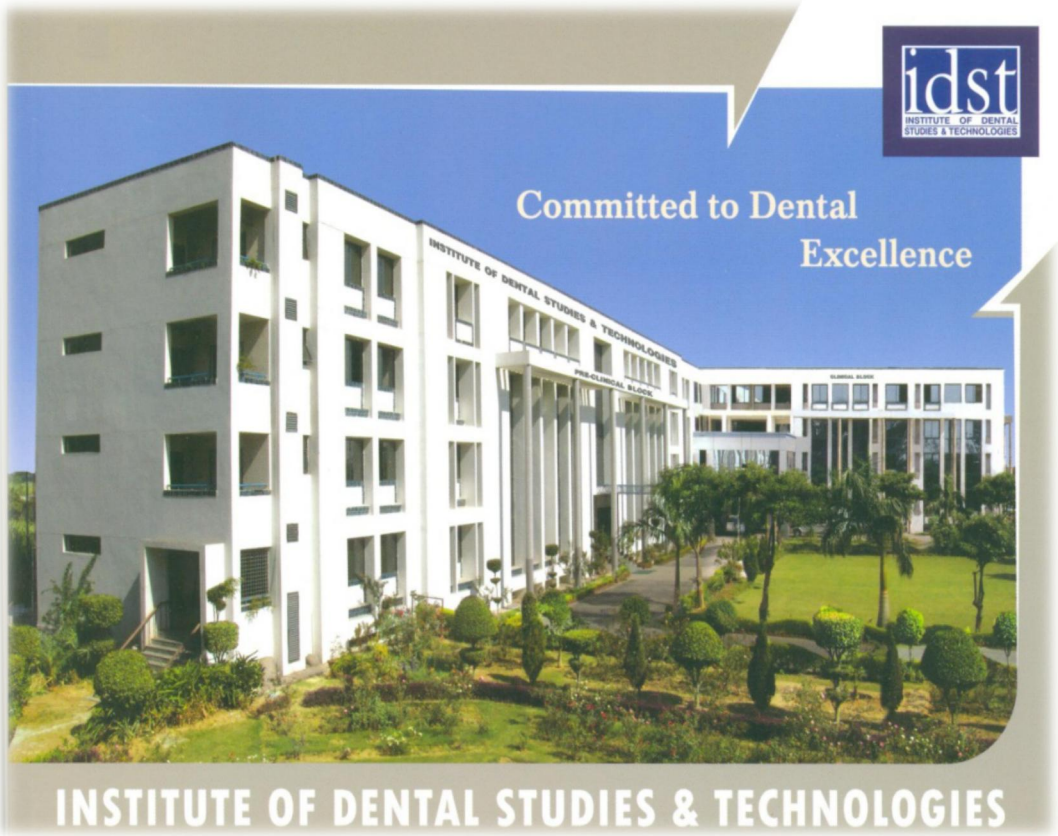
INSTITUTE OF DENTAL STUDIES AND TECHNOLOGIES

INSTITUTIONAL ETHICAL COMMITTEE

(IEC IDST)



STANDARD OPERATING PROCEDURES

INSTITUTE OF DENTAL STUDIES AND TECHNOLOGIES, MODINAGAR

STANDARD OPERATING PROCEDURES FOR INSTITUTIONAL ETHICAL COMMITTEE, IDST

(IEC IDST)

Standard Operating Procedures for Institutional Ethical Committee, IDST (IEC IDST) is a content of Compendium on scientific research and publications at IDST, Modinagar.

1. Introduction: SOP

Standard Operating Procedures (SOPs)

ICH-GCP guideline defines SOPs as "Detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs provide the essential link between the guideline on one hand and the actual practice on the other. It is but natural therefore that, all the individual participants,

performing their primarily required duty or a specific job and belonging to each and every category of the stakeholder has not only to have a well defined SOP but also to observe/follow it very carefully. It goes without saying, therefore, that each stakeholder has to have separate SOPs and IEC is no exception to the rule.

SOP is for the methodical functioning of any important work to be undertaken, a proper, stepwise, work procedure is necessary. In general, in any SOP the steps given should be reproducible, e.g. in the case of clinical trials, it will be neither proper nor acceptable to have an SOP that can be applied to just one or specific clinical trial. Broadly speaking SOPs can be in four different areas covering (i) organization of study in general, (ii) prior to study, (iii) Actual or during, and (iv) End of the study.

2. Role of Institutional Ethics Committee (IEC)

2.1 It will be the responsibility of the IEC to ensure that all research involving human participants shall be conducted in accordance with the basic and general principles of research as outlined by ICMR.

2.2 The IEC shall assess the benefits and risks involved in the research and evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it.

2.3 All aspects of the informed consent process shall be followed.

2.4 The IEC shall ensure that the privacy and confidentiality of the research participants is maintained by the researcher/ research team/ organization.

2.5 The IEC will be responsible for maintaining the distributive justice in the research and give particular attention to wherever the participants are from vulnerable section of the society.

2.6 All proposals shall be reviewed thoroughly before the commencement of the study and adequate measures shall be taken to provide payment or compensation to the participants wherever required.

2.7 The IEC will monitor the study periodically till completion. Site visit can also be initiated at the discretion of the committee.

2.8 The IEC shall be responsible for ensuring the benefit of the research participants and concerned communities, while taking into consideration the interests and need of new research, and having due regard for the requirement of relevant regulatory and applicable laws.

3. Membership Requirements of Ethics Committee

3.1 The Ethics Committee shall be cross-disciplinary and multi-sectoral, consisting of of 7-10 members as guided by the ICMR guidelines.

3.2 The composition of the EC shall be as follows:

a) Chairperson / Vice Chairperson: Shall be non – affiliated to the institution and having prior experience of having served/serving in an EC.

b) Member Secretary: Shall be affiliated and a staff member of the institution having knowledge and experience in clinical research and ethics.

c) Basic Medical Scientist(s): May or may not be affiliated and shall be a non-medical or medical person with qualifications in basic medical sciences/a pharmacologist.

d) Clinician / Health practitioners: May or may not be affiliated and shall consist of 3-5 clinicians with recognized qualification, expertise and training.

e) Legal expert(s): May or may not be affiliated and shall have a basic degree in Law from a recognized university, with experience and training with medical law (desirable).

f) Social scientist/ philosopher/ priest/ an NGO involved in health-related activities. May or may not be affiliated

g) Lay person(s): Shall be non-affiliated, a literate person from the public or community and a representative of the community who has not pursued any medical/ health related activities in the last 5 years.

4. Terms of Reference for EC members

4.1 The head of the institution shall appoint all EC members, including the Chairperson.

4.2 The letter of appointment shall specify:

i. Role and responsibility of the members in the committee
ii. Duration of appointment
iii. Conditions of appointment

4.3 The term of EC membership shall be initially for a period of 3 years. At the end of the stipulated 3 years, the Board can be reconstituted and evaluation of the existing members shall be carried out in terms of regularity in attending EC meetings.Appointment of new members can be done in case if any member wishes to resign or loss of a member, according to ICMR guidelines.

4.4 Members to be appointed should be willing to fulfil the EC requirements.

5. Conditions of Appointment and Quorum

5.1 The conditions of appointment of members shall be as per the guidelines of ICMR

5.2 All the members of the EC shall be required to undertake the review of Research proposals and participate in meetings of EC and monitor anyongoing research.

5.3 EC meetings shall take place once every quarter. Every EC member shall commit to spending minimum of 2 meetings in a year for ethical review and some additional time needed for reviewing proposals and visiting projects. All members shall be required to read all protocols sent to them and participate in the discussion during the meeting for ethical review to ensure that they conform to the guidelines used by the EC. The only exception is for any Member with a conflict of interest with a particular proposal.

5.4 All the Members shall be expected to allocate the required time for meetings as per the agreed annual calendar of the meetings. If, for some unavoidable reasons, a Member is not able to attend the meeting, he/she shall give prior intimation to Member Secretary at the earliest so as to make arrangements for his/her substitution, if required. The Member shall communicate to the Member Secretary the review report with respect to the proposals allocated for review in advance before the meeting.

5.5 A Member can be replaced in the event of: Death, Resignation, Long-term non availability, inability to attend/participate in even one meeting during the year; or if his/her actions are not commensurate with the responsibilities of the EC membership as judged by a 2/3rd majority of the EC Members.

5.6 All Members shall maintain absolute confidentiality of all discussions during the meeting. The Members shall not discuss matters related to EC deliberations with anyone other than EC Members. All personal copies of documents and emails related to the proposal shall be destroyed immediately.

5.7 Conflict of interest(s), if any, shall be declared by Members of the EC. As a rule, any Member who is directly associated with a research proposal must recuse themselves from discussions and decisions related to that particular protocol.

6. Quorum requirements

The quorum requirements shall be followed as per ICMR guidelines:

6.1 A minimum of five members shall be present in the meeting room.

6.2 The quorum shall include both medical, non-medical or technical and/or non technical members.

6.3 Minimum one non-affiliated member shall be part of the quorum.

6.4 Preferably a Lay person shall be a part of the quorum.

6.5 No decision shall be valid without fulfillment of the quorum.

7. SOPs for Vulnerable population

7.1 Vulnerable groups and individuals are those who may be relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens, social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so and thus have an increased likelihood of incurring additional harm.

7.2 The IEC shall ensure that vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.

7.3 If any vulnerable group is to be solely recruited in any research,then the IEC shall ensure that the research is able to answer the health needs of the particular group.

7.4 IEC SHALL monitor that the participants from the vulnerable group are empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation in the research.

7.5 If potential participants lack the ability to consent, a LAR shall be involved in decision making.

7.6 IEC shall take special care to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

7.6.1 The IEC will make arrangements to safeguard the dignity, rights, safety and well-being of these individuals.

8. Training

All IEC members are conversant with the National Ethiical Guidelines for Biomedical and Health Research involving Human participants, 2017. A team of trainers chosen for this purpose by Member Secretary will ensure that new members get trained within a fortnight after being inducted.

Records of such training shall be maintained in IEC office.

8.1 Members should be trained in Human Research Protection, EC functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

8.2 EC members should undergo initial and continuing training in Human Research Protection, applicable EC, SOPs and related regulatory requirements. All training should be documented.

Any relevant updates/ guidelines in the processes of the EC shall be brought to the immediate attention of all Members. Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review by being updated with the latest development in this milieu.

8.3 Any new inducted EC member shall be required to provide the necessary training certificate for GCP/Human Research Protection, within six months of joining.

8.4 Existing EC members are to keep themselves updated about any change in the relevant guidelines or regulatory requirements as provided by the ICMR.

8.5 All EC members are conversant with Guidelines for Research involving Human Subjects. A team of trainers chosen for this purpose by member secretary will ensure that new members get trained within fortnight after being inducted.

8.6 All EC members will be made conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

8.7 Records of such training will be maintained in EC office.

9. Conflict of Interest

9.1 The IEC shall ensure the disclosure of any COI at the level of researchers, EC members, institutions and sponsors.

9.2 If the COI is inherent in the research, it will be required to declare this at the outset and establish appropriate mechanisms to manage it.

9.3 Researchers will be required to ensure that the documents submitted to EC include a disclosure of interest that may affect the research.

9.4 IEC shall evaluate each study in light of any disclosed interests and ensure the appropriate means of mitigation are taken.

9.5 COI within the EC shall be declared and managed accordingly.

10. Offices

10.1 The Chairperson shall conduct all meetings of the EC. In the absence of the Chairperson, an alternate Chairperson shall be elected by the Members present who shall conduct the meeting.

10.2 The Member Secretary shall be responsible for organizing the meetings,maintaining the records and communicating with all those concerned the Member Secretary shall maintain a copy of the minutes/proceedings of the Meetings prepared after approval by the Chairperson, before communicating the same to the researchers. He/she shall issue decision notices to the research team whose project(s) has/have been reviewed after obtaining approval from the Chairperson within 2 weeks of the EC meeting. All EC records will be maintained by the secretary for a period of 5 years from the date of the end of the project.

11. Independent consultants

11.1 The EC may call upon such subject experts as independent consultants who may add or provide valuable opinions of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases and methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or minorities. They are required to give their specialized views but do not take part in the decision - making process of the EC.

12. Application Procedures

12.1 All proposals shall be submitted in the prescribed application form.

12.2 All relevant documents shall be enclosed with the application form.

12.3 The application form in the prescribed format and duly signed by the Principal Investigator(PI) (and Co-investigators/ Collaborators, where appropriate) along with all relevant documents shall be submitted to the EC Secretary.

12.4 Meetings of the IEC shall be held at scheduled intervals and all applications should be submitted to the IEC at least 2 weeks before the date of the meeting.

12.5 On the day of the meeting, the Principal Investigator(PI) or person designated by PI will have to make an oral presentation to the EC and take questions for clarifications.He/she will then leave the room while the proposal is being discussed by the EC.

12.6 The decision of the EC shall be communicated in writing to the PI/researcher.If any revision is to be made in the proposal, the revised document shall be submitted electronically or in person, as recommended by EC, within a stipulated period of time as specified in the communication or before the next meeting.

13. Documentation

13.1 For a thorough and complete review, all research proposals shall be submitted with the following documents: box 4.4

a) Name of the applicant with designation.
b) Name of the Institute/ Hospital / Field area where the proposed research is to be conducted.
c) Detailed protocol of the proposed research.
d) Ethical issues in the study and plans to address these issues.
e) Proposal should be submitted with all relevant enclosures like pro forma, case report forms, questionnaires, follow - up cards, etc.
f) Informed consent process, including patient information sheet and informed consent form/ assent in English and local language(s).
g) For any drug / device trial, all relevant pre-clinical in-vitro and animal data and clinical trial data from other centres within the country/countries, if available.
h) Curriculum vitae of all the investigators with any relevant publications in last five years.
i) Any regulatory clearances required.
j) Sponsor(s) and source(s) of funding.
k) Any other financial issues including those related to insurance.
l) An agreement to report Serious Adverse Events (SAE) to EC.
m) Statement of conflict(s) of interest, if any.
n) Agreement to comply with the relevant national and applicable international guidelines, as applicable.
o) A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ethics Boards or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
p) Plans for publication of results-positive or negative- while maintaining the privacy and confidentiality of the study participants.
q) Any other information relevant to the study.

14. Review procedures

14.1 The meeting of the EC shall be held 4 times a year and any additional meetings may be held if and when required. Such additional meetings will be convened by the chairperson of Sangath in consultation with the chair of the EC.

14.2 The proposals shall be sent to the Members at least 10 days in advance of the scheduled EC meeting.

14.3 Researcher/PI shall make an oral presentation to the EC and take questions for clarifications.

14.4 Researchers shall be invited to offer clarifications if need be.

14.5 Independent consultants/Experts shall be invited to offer their opinion on specific research proposals if and when needed.

14.6 Decisions shall be taken by consensus after discussions.

14.7 The decisions shall be recorded and signed by members present at the meeting and Chairperson's will provide approval in writing.

14.8 All Members of the EC, including those who were not present at the meeting, will be informed of the decision via email.

15. Element(s) of review

15.1 Scientific design and conduct of the study.

15.2 Approval of appropriate scientific review Boards.

15.3 Examination of predictable risks/harms.

15.4 Examination of potential benefits.

15.5 Procedure for selection of subjects in methodology including inclusion/ exclusion/ withdrawal criteria and other issues like advertisement details. Criteria for withdrawal of patients, suspending or terminating the study.

15.6 Management of research related injuries, adverse events and serious adverse events.

15.7 Compensation provisions.

15.8 Patient information sheet and informed consent form in local language.

15.9 Protection of privacy and provision of confidentiality.

15.10 Involvement of the community, when and where necessary.

15.11 Plans for data analysis and reporting, along with safety and quality assurance report(s).

15.12 Competence of investigators, research and supporting staff.

15.13 Facilities and infrastructure of study sites.

In case of Clinical trials:

15.14 Justification for placebo in control arm, if any.

15.15 Availability of products after the study, if applicable.

15.16 Adherence to all regulatory requirements and applicable guidelines.

16. Expedited review

16.1 In exceptional circumstances an application requires urgent review and EC approval (e.g. an urgent call for proposal which cannot wait for the next quarterly meeting) – in such cases expedited review may also be taken up after consideration of the circumstances by the Chairperson and the Member Secretary. The concerned PI shall approach the Chairperson through the Member Secretary and shall be able to explain and convince the chair the need for an expedited review. A sub-committee will then be convened by the Chairperson to review the proposal and make a decision. Approval given in such situations will be provisional and subject to ratification at the next full committee meeting. Expedited reviews are considered acceptable in minimal risk studies where minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (*United States Department of Health and Human Services Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects).*

17. Decision-making procedures

17.1 Members shall discuss the various issues before arriving at a consensus.

17.2 Member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

17.3 Decisions shall be made only in meetings when quorum is complete.

17.4 Only EC Members can make decision(s). The expert consultants shall only offer their opinions.

17.5 Decision(s) may be to a) approve, b) reject or c) conditional acceptance subject to receipt of further information/modifications. Specific suggestions for modifications and reasons for rejection shall be duly communicated to the researcher.

17.6 In cases of conditional decisions, clear suggestions for revision and the procedures for having the application re-reviewed, if deemed necessary should be specified.

17.7 Modified proposals may be reviewed by an expedited review by the Chairperson and he/ she can invite other Members to examine the revised application and if the EC recommendations have been adhered to the applicant will be given the required approval by the Chairperson.

18. Communication within the EC and those concerned herewith

18.1 Decision(s) taken by the EC shall be duly communicated by the Member Secretary in writing to all the Members of the EC and those concerned directly/indirectly with such decisions.

18.2 Suggestion(s) for modifications in the proposal/ protocol, if any, shall be duly communicated to the researcher by the EC.

18.3 Reason(s) for rejection of the proposal/ protocol shall be duly informed to the researcher(s) with reasons for the same.

18.4 The schedule/ plan of ongoing review by the EC shall be communicated to the Principal investigator (PI).

19. Appeal procedures

19.1 This procedure is designed to deal with the following two situations:

19.1.1 Where the EC has rejected an application for ethics approval (for reasons other than the application being incomplete) and the researcher applicant wishes to appeal.

19.1.2 Where the EC has approved an application for ethics approval subject to some changes being made and the researcher disagrees with the proposed changes. In this case, before making a formal appeal, the researcher should initially confer with the Chairperson for clarification of the reasoning of the EC. After this consultation, if the researcher is not satisfied then she/he can make a formal appeal as outlined below.

19.1.2.1 If the Researcher wishes to appeal a decision made as part of the approval process, s/he must notify the Chairperson of the EC through the Member Secretary. The appeal shall be in writing and must be sent via post or email within fourteen days of being notified of that decision.

19.1.2.2 The Chairperson can appoint a committee independent of the EC who will then review the application and give recommendations to the EC.

19.1.2.3 The membership of the Panel shall be at the discretion of the EC Chairperson.

19.1.2.4 Once the panel has reached its decision, the panel Chairperson can give the recommendations of the committee to the EC and based on the recommendations the EC can make an amended decision. This decision cannot be appealed against, using the procedure described above.

20. Follow up procedures

20.1 All ongoing projects that have been given ethical approval have to submit their annual reports to the EC at 12 months after approval was granted. These would then be tabled at the next EC meeting.

20.2 Final report shall be submitted at the completion of the study.

20.3 Depending on the risk involved, the progress of the proposal may bemonitored at shorter intervals(half yearly/ quarterly) per EC decision. Approval may be continued if progress is satisfactory.

The EC shall continually evaluate progress of ongoing proposals, review SAE(serious advert events) reports from all sites along with protocol deviations/ violations and non compliance.

20.4 The EC shall examine the management of any SAEs and decide the compensation for research-related injuries if applicable. All serious adverse events have to be reported to the EC.

All protocol deviation(s), if any, shall be promptly informed with adequate justifications for the same to the EC Chairperson. The Chairperson will then decide if fresh approval is indicated. Any major deviations (such as change in design, target sample, inclusion of a new intervention component) will require re-submission for fresh approval.

20.5 If the violations are serious the EC may halt the study and inform the institutional head and concerned authority where there is continuing non-compliance to ethical standards.

20.6. All such information shall be recorded and communicated to the EC through the annual reports.

21. Record keeping and Archiving

21.1 All documentation and communication of the EC shall be dated, filed and preserved and confidentiality shall be maintained during access and retrieval procedures. The EC shall be required to maintain the following records for a period of at least 3 years after the completion/ termination of the study. Records may be archived for a longer duration if required by a sponsor/ regulatory body.

22. Resignation/ Replacement of members

22.1 Members of IEC will be appointed for period of three years initially which could be extended for one more term. Extension of membership will be based on the recommendation of the Chairman and Member Secretary of IEC.

22.1.1 Policy for removal of member

A. A member may be relieved or terminated of his/her membership in case of conduct not suitable for a member of the Ethics Committee.

B. Inability to participate even a single meeting on any grounds for one calendar year.

C. In all such situation/circumstances, Member Secretary will serve a letter of termination to the member.

D. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted EC meeting and EC membership circular/roster will be revised.

22.2 The members who have resigned may be replaced by the discretion of the appointing authority for the same.

22.3 EC members who decide to resign must provide the Chairman & member secretary of EC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.

22.4 In case of resignation, Chairman & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.