All research activities done in the institution must be approved by the Institutional Ethics Committee (IEC) prior to the commencement of actual empirical work. IEC adheres to the latest ICMR's Guidelines on preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee towards Human Research

CONDITIONS OF APPOINTMENT AND QUORUM REQUIRED TOWARDS THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Chairman

Chairman is appointed for a period of 5 years by the Principal, as ratified by The Board of Trustees, SVS Education Society. The appointment may be renewed by the Chairman, SVS Education Society under the recommendation of the Principal, SVS Institute of Dental Sciences for an additional term.

EC Members

EC members are appointed for a period of 3 years by the Principal, SVS Institute of Dental Sciences. The Ethics Committee will include staggered appointment of new members by ensuring that a mixture of newer and experienced members are present at every meeting. Prospective members within the institution are allowed to observe the proceedings and study IEC records of at least 3 IEC meetings to prior to their induction into the EC.

Member-secretary

Member-secretary is appointed for a period of 2 years by the Principal, SVS Institute of Dental Sciences on the strong recommendation of the Academic committee, SVS Institute of Dental Sciences which oversees academic and research content generated by the institution. The secretary **must** be an EC member prior to his appointment as Member-secretary.

Quorum of ethics committee

The nominal composition of the IEC (maximum 15 members) is as follows. 4-7 members from various dental specialties

- Chairman
- 3-7 members from various dental specialties
- Member secretary
- 1-3 member(s) from the allied medical college
- 1 legal expert
- 1-2 members who are two social scientists or representatives of non-government agencies
- 1 lay person

The ***minimum quorum*** required (10 members) to declare an IEC meeting as valid or binding is as follows:

1. Chairman of the IEC- **Compulsory** attendance
2. Member secretary- **Compulsory** attendance
3. 1 Lay person- **Compulsory** attendance
4. 3 members from Dental Specialities- **Minimum** attendance

5. 2 members from medical specialities- **Minimum** attendance
6. 1 legal expert
7. 1 sociologist

INSTITUTIONAL ETHICS COMMITTEE (IEC) POLICY TO MONITOR OR PREVENT CONFLICT OF INTEREST (COI)

1. **SOPs to be followed by the PIs to avoid conflicts of interest**

   All PIs should voluntarily disclose any

   a. ***Financial interest*** in the form of a paid position, grants, compensation or royalties from a commercial sponsor of clinical research/clinical trial
   b. ***Non-financial interest*** in an event wherein, the PI has a personal relationship with a member of a sponsoring organisation or with member of the IEC

2. **SOPs to be followed during constitution of the IEC**
   a. COI should be avoided while selecting EC members
   b. Any institution administrators including the principal and the vice-principal should not serve as members of EC as their presence may undermine the independence of the EC.
   c. Similarly, an individual who is related to the management should not serve as member of EC.

3. **Process to be followed to manage COI during IEC deliberations and decisions**
   a. Every EC member should sign a COI agreement before ethical review tasks of the EC commence
   b. EC members should disclose in writing to the member secretary all real, potential, or perceived COI interest for themselves and their family members– spouse, children, friends, or their professional associates when submitting a proposal
   c. Such disclosure shall be sufficiently detailed and timely to allow the IEC administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet quorum
   d. If an investigator is a member of the EC, he/she cannot participate in the review and approval process for any project in which he/she is involved as principal investigator, investigator, co-investigator, or sub-investigator or has any other potential COI
   e. It will also be a best practice for the EC member who is the investigator to send another e-mail to the member secretary/designee to remind about his/her COI when the proposal comes up for EC deliberation
   f. At the beginning of each convened EC meeting, the chairperson/member-secretary will ask the EC members if anyone has a financial or nonfinancial COI with regard to any of the research projects on the agenda for reviewed at the meeting
   g. The chairperson/member-secretary should review disclosures, to determine whether a COI exists and to determine appropriate management of the COI
   h. Any EC member, who has COI in a clinical research project, should abstain from deliberations and the decision-making process, except to provide information as requested by the EC. Such abstentions should be documented in the minutes
   i. If any unanticipated COI affects quorum, that project proposal should not be discussed and should be deferred to the next scheduled meeting
   j. In case the member-secretary of the EC is principal investigator, investigator, co-investigator, or sub-investigator for project under discussion, he/she should

declare COI and leave the meeting room. Another EC member nominated as Acting Member Secretary will perform the function of the secretary

k. Care should also be taken that all queries (e.g., from patients, others) on the project during its life are managed by the acting member secretary
l. In case of several projects being discussed in the meeting, the minutes should clearly delineate the projects where the members secretary had a COI and hence was not part of the decision-making process. Ideally, separate minutes for these projects should be issued with the acting member secretary signing the minutes
m. The EC **should not approve** a clinical research study where a COI is not eliminated.

SVS Institute of Dental Sciences
committed to science - to care with compassion

MEMBERSHIP REQUIREMENTS OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

1. The IEC will be gender neutral and gender equal
2. 8 to 15 members (hereafter referred to as ***EC members***) from various dental specialities and with individuals from medical, legal and sociology backgrounds will constitute the panel.
3. The committee will broadly consist of
    - One **chairperson**, who will lead and appraise the committee of on its duties and functions.
    - 3-7 members from various dental specialities
    - 1-3 member(s) from the allied medical college from basic sciences stream including anatomy, physiology, biochemistry, molecular biology, pharmacology, microbiology and pathology.
    - 1 legal expert
    - 1-2 members who are two social scientists or representatives of non-government agencies
    - 1 lay person to have a common-man's perspective on the research proposals
    - 1 **member-secretary** who is responsible for the functioning of the committee and record-keeping after every session.

General requirements of all EC members

Selected members (Age>35 years; Post graduate degree in respective field) should possess the necessary research experience, scientific knowledge and expertise- They will be accepted into the committee after their research activities in the form of a) publications b) ongoing activities c) grants obtained and d) past activities pertaining to ethics in research is thoroughly vetted by the **member-secretary**; knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IEC work is absolutely mandatory. An educated member from a non-science background (Age>35 years) shall be considered as a lay-person. All the appointments will be at the discretion of the Principal, SVS Institute of Dental Sciences.

Requirement for the post of Chairman of the Ethics committee

A Chairperson (Age>50 years) **not** affiliated to the Institute will head the IEC to ensure an unbiased functioning of the Committee. The chairman should have been a member of his institutes own IEC and should lead over all the other EC members when metrics such as a) publications b) ongoing activities and c) grants obtained are considered. Decision to appoint a chairman will rest on the Principal of the Institution and will be ratified by The Board of Trustees, SVS Education Society.

Requirement for the post of Member-secretary of the Ethics committee

On rotation every 2 years, an individual who is professor and above with at least 2 internationally indexed publications and with at least 2 grants obtained from government or private agency will be appointed as member-secretary. Decision to appoint a member-secretary will rest on the Principal of the Institution and the Academic committee, SVS Institute of Dental Sciences.

PROCEDURE FOR RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Resignation

Chairman can resign from his post by submitting a letter of resignation to the Principal, SVS Institute of Dental Sciences. EC members may resign from their post by submitting a letter of resignation to the Chairman, IEC. Member Secretary can resign from his post by submitting a letter of resignation to the Principal, SVS Institute of Dental Sciences. All members are expected to notify their intention of resignation at least **3 months** prior to the next IEC meeting.

Replacement

First preference is given to the observer pool comprising of enterprising faculty who have observed at least 3 IEC meetings. In their absence, Faculty who are above Professor grade or independent consultants with requisite qualifications may be appointed based on the suggestions of the Chairman, IEC and/or the Principal, SVS Institute of Dental Sciences.

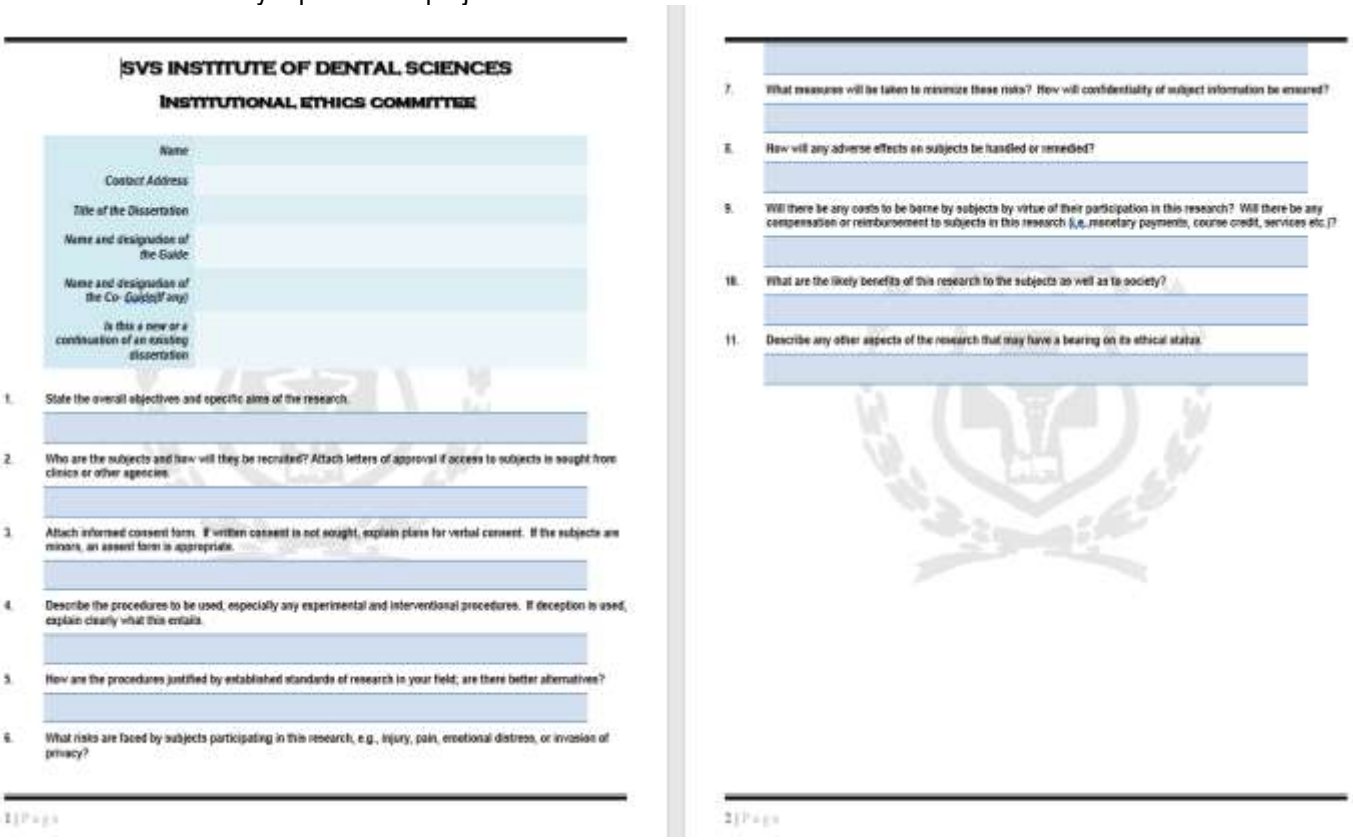
Removal

Members may be removed for the following reasons

1. Absent for **two** consecutive meetings
2. Not complying to the responsibilities set for the members
3. Not willing to abide by the requirements laid in the SOPs
4. Unsatisfactory accountability towards reimbursement for services rendered
5. Unwilling to abide by Conflict-of-Interest Agreements regarding meeting deliberations, applications, information on research participants and related matters

GENERAL STANDARD OPERATING PROCEDURES (SOPs) OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

1. **Application:**
   a. The academic committee of the institution, which oversees all research activity identifies proposals with ethical issues and directs the researcher to apply for IEC clearance.
   b. All proposals should be submitted in the prescribed application form *(below)* and a synopsis of the project/dissertation must be enclosed with it.



SVS INSTITUTE OF DENTAL SCIENCES

INSTITUTIONAL ETHICS COMMITTEE

Name	
Contact Address	
Title of the Dissertation	
Name and designation of the Guide	
Name and designation of the Co- Guide(If any)	
Is this a new or a continuation of an existing dissertation	

1. State the overall objectives and specific aims of the research.
2. Who are the subjects and how will they be recruited? Attach letters of approval if access to subjects is sought from clinics or other agencies.
3. Attach informed consent form. If written consent is not sought, explain plans for verbal consent. If the subjects are minors, an assent form is appropriate.
4. Describe the procedures to be used, especially any experimental and interventional procedures. If deception is used, explain clearly what this entails.
5. How are the procedures justified by established standards of research in your field; are there better alternatives?
6. What risks are faced by subjects participating in this research, e.g., injury, pain, emotional distress, or invasion of privacy?

1 | Page

7. What measures will be taken to minimize these risks? How will confidentiality of subject information be ensured?
8. How will any adverse effects on subjects be handled or remedied?
9. Will there be any costs to be borne by subjects by virtue of their participation in this research? Will there be any compensation or reimbursement to subjects in this research (i.e.,monetary payments, course credit, services etc.)?
10. What are the likely benefits of this research to the subjects as well as to society?
11. Describe any other aspects of the research that may have a bearing on its ethical status.

2 | Page

   c. **Three** 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 forwarded by the Head of the Departments / Institution to the ethics committee.
   d. The date of meeting will be intimated to the researcher who will then present his project (in a stipulated time of 8 *mins*) in front of the committee with emphasis on the ethical aspect of his project.

2. **Documentation:** All research proposals should be submitted with the following data.

Name
Contact Address
Title of the Dissertation
Name and designation of the Guide
Name and designation of the Co- Guide (If any)
Is this a new or a continuation of an existing dissertation?
1.State the overall objectives and specific aims of the research.

2.Who are the subjects and how will they be recruited? Attach letters of approval if access to subjects is sought from clinics or other agencies.
3.Attach informed consent form. If written consent is not sought, explain plans for verbal consent. If the subjects are minors, an assent form is appropriate.
4.Describe the procedures to be used, especially any experimental and interventional procedures. If deception is used, explain clearly what this entails.
5.How are the procedures justified by established standards of research in your field; are there better alternatives?
6.What risks are faced by subjects participating in this research, e.g., injury, pain, emotional distress, or invasion of privacy?
7.What measures will be taken to minimize these risks? How will confidentiality of subject information be ensured?
8.How will any adverse effects on subjects be handled or remedied?
9.Will there be any costs to be borne by subjects by virtue of their participation in this research? Will there be any compensation or reimbursement to subjects in this research (i.e., monetary payments, course credit, services etc.)?
10.What are the likely benefits of this research to the subjects as well as to society?
11.Describe any other aspects of the research that may have a bearing on its ethical status.

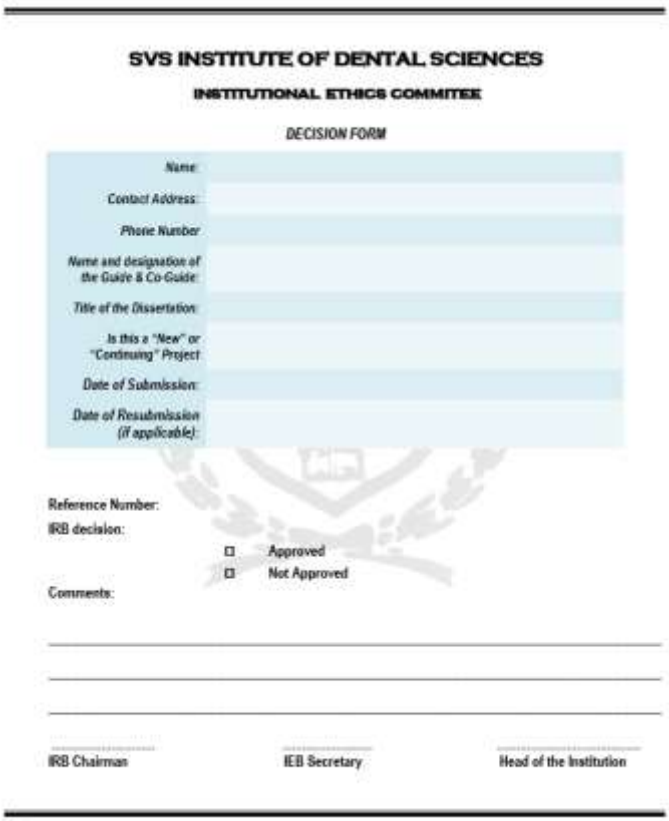
3. Review Procedure

a. Meetings of the IEC will be held annually for dissertations and on a case-by-case basis for independent studies and studies soliciting external funding.
b. The proposals will be sent to members at least ***2 weeks*** in advance.
c. Decisions will be taken by consensus after discussions, and voting will be done if necessary. The Chairman's decision will remain final and binding in case of a tie.
d. PI should be available during the meeting and may be asked to clarify on certain aspects.
e. Only IEC members will make the decision in the absence of investigators, and faculty involved in the research.
f. Decision may be to approve or revise the proposals. Clarifications will be offered to the PI. *Improper justification may result in rejection of the proposal.*
g. Revised proposals may be subjected to an expedited review with the committee convening within a month to offer a final decision.

4. Communication of the Decision

The decision of the committee will be communicated in writing through a certificate issued to the researcher *(below)*. 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 decisions of the meeting shall be recorded in the minutes book and shall be confirmed

(PTO)



SVS INSTITUTE OF DENTAL SCIENCES

INSTITUTIONAL ETHICS COMMITEE

DECISION FORM

Name:	
Contact Address:	
Phone Number	
Name and designation of the Guide & Co-Guide:	
Title of the Dissertation:	
Is this a "New" or "Continuing" Project	
Date of Submission:	
Date of Resubmission (if applicable):	

Reference Number:

IRB decision:

☐ Approved

☐ Not Approved

Comments:

IRB Chairman IEB Secretary Head of the Institution

3 | Page

5. Record Keeping

All the 1. Applications received towards issual of IEC certifications 2. Deliberations on research proposals 3. Accepted and Rejected applications and 4. Minutes are bound into a hard and soft copy and are filed for the institute's perusal. Head Office in-charge & Academic committee will function as a sub-committee and ensure proper filing and disbursal of records pertaining to the IEC.

STANDARD OPERATING PROCEDURES TO BE FOLLOWED BY THE INSTITUTIONAL ETHICS COMMITTEE (IEC) COMMITTEE FOR VULNERABLE POPULATIONS

1. **Definition of Vulnerable populations** *(as per the ICMR-NIRRH Ethics Committee recommendations for Clinical Studies in Vulnerable Population, 2019)*
   As pertaining to dentistry, the following will be considered as vulnerable populations or study cohorts
   a. Subjects with genetic defects
   b. Socially disadvantaged subjects
   c. Mentally challenged subjects
   d. Subjects providing consent under duress
   e. Terminally ill subjects
   f. Pregnant and Lactating women
   g. Children
   h. Tribals and marginalized communities
   i. Refugees &
   j. Subjects with rare diseases

2. **Review Procedure in case of a study involving vulnerable groups**
   The following procedure will be followed to ensure proper justification of the study in vulnerable populations

No	***Activity***	***Responsibility***
1	Identification of a research proposal on vulnerable populations	Academic Committee
2	Submission of these projects to the IEC	Academic Committee IEC Office
3	Review of protocol and assess whether their inclusion is justified	IEC
3.5	[redacted] ***Rejection of the proposal if no adequate justification is provided by the PI***	***IEC Chairman*** ***Member Secretary***
4	Ensure measures for protecting rights and interests of vulnerable population	*IEC Chairman* *Member Secretary* *Legal Representative*
5	Review the IEC application and suggest modifications accordingly	IEC

3. **Special needs and Measures for projects involving vulnerable populations**
   a. Dual consent of a guardian and a care giver (if present) is a must
   b. Refusal of participation of a subject in the project must be respected at all costs
   c. Research must be conducted only after obtaining additional legal or regulatory permissions if they are required as per the applicable laws and must be registered accordingly in an appropriate registry.
   d. The standard regimen of care should not be disturbed unless there is a compelling and justifiable reason to do so.

SVS Institute of Dental Sciences
committed to science - to care with compassion

TERMS OF REFERENCE OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

1. **Purpose:** The primary function of the IEC is to review research proposals involving human participants and their data to ensure that they agree with local and international ethical guidelines.
2. **Functions:** The IEC serves to
    a. ensure that the rights of research participants are protected
    b. address the legal, regulatory, and professional issues that may surround the research proposal
    c. ensure that the medical experimentation and human subject research are carried out in an ethical manner.
3. **Responsible to:** The Board of Trustees, SVS Education Society.
4. **Composition**

Member(s)	Method of Appointment	Tenure
Chairman	Principal, ratified by The Board of Trustees, SVS Education Society.	5 years
EC members • 3-7 members from various dental specialties • 1-3 member(s) from the allied medical college • 1 legal expert • 1-2 members who are two social scientists or representatives of non-government agencies • 1 lay person	Principal, SVS Institute of Dental Sciences	3 years
Member Secretary	Academic committee, SVS Institute of Dental Sciences	2 years
Sub-Committee	Head Office in-charge & Academic committee to ensure proper filing and disbursal of records pertaining to the IEC	-

5. **Venue:** Seminar hall, Department of Periodontics, SVS Institute of Dental Sciences
6. **Minutes:** Minutes are recorded at each meeting and are sent to the monitoring committees. They are also appended in the yearly bound-record generated after every meeting.
7. **Records:** All the 1. Applications received towards issual of IEC certifications 2. Deliberations on research proposals 3. Accepted and Rejected applications and 4. Minutes are bound into a hard and soft copy and are filed for the institute's perusal.
8. **Functioning:** All the applications will be forwarded to the members 2 weeks in advance of the proposed meet. Following which, appropriate records are generated and IEC clearance certificates will be issued based on the merits of the application. All communications and activities will be transcribed into a record (as mentioned above) and will be conveyed to the Principal, Academic committee and the Board of Trustees.

SVS Institute of Dental Sciences
committed to science - to care with compassion

POLICY REGARDING TRAINING FOR NEW AND EXISTING COMMITTEE MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

The institute has tied up with independent agencies and existing faculty to train new and existing members on the intricacies of ethics in clinical research. The course is held biannually in June and December under two modules;

Module 1 *(1 day)* aimed at *new members* and includes

a. fundamental principles in medical ethics *(45 mins)*
b. ethical reasoning and argumentation *(30 mins)*
c. ethical dimensions in a study *(30 mins)*
d. Working of the IEC *(45 mins)*
e. Legal aspects of ethics *(45 mins)*

Module 2 *(1 day)* aimed at *new & Existing members* and includes

a. ethical principles and their application in biomedical research *(1.5 hrs)*
b. research design and methods *(1.5 hrs)*
c. practicalities of conducting research *(1 hr)*

Training is designed to be responsive to requests from IEC members and a certificate of participation is issued after completion of training.