DAPM RV DENTAL COLLEGE

Compendium of

Bioethical Guidelines and
Standard Operating Protocols [SOP]
for Institutional Ethics Committee.

Operational guidelines to facilitate the IEC process in a Dental institution in India.

July 2021

DAPM RVDC Research , Sustenance & IRB Committee
and Department of Public Health Dentistry Initiative

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July 2021

Drafted By:

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Institutional Research Sustenance and Institutional Review Board Committee

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INDEX

From the Principal's desk

Research is one of the cornerstones of a pioneer educational institution where research becomes a culture of that institution. The integration of research into the work culture of an institution is a long-drawn process. I am proud of one such initiative by the IRB/IEC of DAPMRV Dental College, which has brought out a comprehensive book on guidelines and SOPs for submitting a research proposal.

The research subcommittee of the institutional IRB has had multiple brainstorming sessions and has come out with this wonderful book, which, I am sure, will be like a road map for carrying out research in our institution. This document is a translational of the vision of founder Principal Dr KS Nagesh which the research subcommittee consisting of Dr Harikiran AG, Dr Deepti Vadavi, Dr Sarita Yanduri and Dr Subhash BV has brought into a form of document with meticulous efforts. The committee had reviewed a number of publications and documents and through a consultative process, have taken the best practises from these documents and incorporated them into this book.

I am extremely happy to announce that this book is one of the very few such publications from a dental institution and I am optimistic that it will be a source of reference for such similar projects in other institutions.

Dr. Asha R Iyengar

Principal

Editorial Team Note:

The Institutional Review Board of DAPM RV Dental College has been functioning from several years and is an integral part of the research policy of the institution. Over the years, the Board has been striving to evolve towards policies adopted by reputed bodies such as Indian Council of Medical Research and protocols set by the World Health Organization.

After a thorough review of literature and keeping in mind the need to consolidate the guidelines and to formulate a policy tailor made for our institution, it was decided that a document with the standard operating procedures to be followed by the IRB should be developed which would be dental institution specific. This along with the fact that registration of the Institutional Review Board with ICMR is mandatory, motivated us to further develop this document so as to streamline the entire process of submitting a research proposal in the institution. The faculty and students both undergraduate and postgraduate students were keen on taking up research projects in their areas of interest. It was noticed that often the students who had never been exposed to research previously found it difficult to draft their synopsis. By coming out with a detailed SOP, we felt this document will help to guide them as well as to improve the quality of the research proposals.

Over the past six months the team has taken a lot of efforts to formulate this SOP and has included not only the guidelines but also checklists and forms which will standardize the entire procedure. Extensive review of IRB documents of reputed institutions like ICMR, NIMHANS etc. was carried out. Best practices from these documents were analyzed and customized to the needs of the institution.

The SOP includes guidelines with regards to constitution of IRB, quorum, conduct of meetings, application procedure, follow up etc. This document also has customized checklists for submission of research proposals and formats for the same. It also highlights the procedures to be followed while submitting the interim and final reports of the research.

We hope that this comprehensive document will be useful while applying for research grants, publication in journals with high impact factor and conduct of research in the right direction. It will be a step towards achieving our institutional Vision and Mission with regards to excelling in research. These published guidelines will also be constantly monitored and updated as per the changing guidelines of the University, apex bodies and eminent research bodies.

Dr Harikiran A.G.
Editor in Chief

Dr Deepti Vadavi
Dr Sarita Yanduri
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Research Subcommittee Members

Compendium of Bioethical Guidelines and Standard Operating Protocols [SOP] for Institutional Ethics Committee. - ***Operational guidelines to facilitate the IEC process in a Dental institution in India.***

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Abstract:

DAPM RV Dental College believes in promoting research at all levels. The Institutional Review Board forms one of the important pillars for maintaining high standards of integrity and accountability in the conduct of academic research. This document developed by the research subcommittee of the Institutional Review Board provides a comprehensive set of guidelines and standard operating procedures to be followed during the submission and conducting of quality research in the institution. The document hopes to allow seamless and effective functioning of the IRB and helps to strengthen the research policy of the institution. The information in this document is sourced from the best practices of other institutions ICMR Ethical Guidelines for Biomedical Research, Code of Ethics in Academic research from European University Institute, Standard operating procedures of Institutional review Boards of institutions - Dr DY Patil Medical College, Hospital and Research Centre, Navi Mumbai, All India Institute of Medical Sciences Bhubaneswar, PSG Institute of Medical Sciences and Research, Coimbatore.

This document contains details of all the procedural requirements of all IRB/IEC functioning. This document may serve as a referral by the committee during any ethical issues/conflicts. It provides an overview for constituting the IRB, role of IRB, mandate of IRB, terms of reference, composition, membership of IRB, roles played by the members, conduct of meeting, role of independent consultants, application procedures and schedule of IRB meetings and documentation of proposals and review procedures. This document also gives an overview of the timeline of the review process with elements of review and types of review. A detailed step by step procedure about decision making of the research proposals and cases for certificate of exemption is given. A detailed explanation of communicating the decision of the IRB and follow up procedures are incorporated in this document. It also touches on administration and management aspects of IRB and special considerations and steps taken to protect the vulnerable population. The document concludes with a note on budgetary allocation for the external IRB members and IRB fee for the proposal from a PhD candidate.

Bioethical Guidelines and Standard Operating Procedure (SOP) for Institutional Review Board/Institutional Ethics Committee (IRB/IEC) for Human Research at DAPM RV Dental College, Bangalore

The Research Sustenance and Institutional Review Board/Institutional Ethics Committee will follow all ethical guidelines for biomedical research as provided by the Indian Council of Medical Research (ICMR). The guidelines have been modified to suit the dental scenario. Presently, The Standard Operating Procedures are in alignment with the latest ICMR Guideline document for biomedical research 2017. These guidelines will be reviewed and updated as per the changing guidelines/circumstances of ICMR, Dental Council of India, University or institution.

1. Objective:

The objective of Standard Operating Procedure (SOP) is to contribute to the effective functioning of the institutional ethics committee to ensure quality and consistency in review of clinical research proposals in accordance with the ICMR and national ethical guidelines for biomedical research on human subjects.

2. Mandate of IRB/IEC:

To review the research proposals in entirety and act as guardians of dignity, rights, privacy, safety and well-being of research participants.

3. Authority Under which Institutional review Board/Institutional Ethics Committee (IRB/IEC) is constituted:

The head of the institution will constitute the IRB/IEC.

4. Role of Institutional Review Board/Institutional Ethics Committee (IRB/IEC):

- All research including research involving human participants conducted in the institution shall be reviewed by the committee.
- IRB/IEC shall function with a mandate to safeguard the dignity, rights, privacy, safety and well-being of research participants irrespective of the source of funding.
- The committee shall make sure that all cardinal principles of research ethics viz, autonomy, beneficence, non–maleficence and justice are taken care during the entire study period and also while publishing the findings of the study conduct.
- The committee shall look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required.
- The committee shall review the proposals before the start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc.

- The committee shall also ensure compliance with all regulatory requirements, applicable guidelines and laws.

5. Terms of Reference:

- Ensure the highest ethical and scientific standards of research at DAPM RV Dental College.
- Review and approve proposals for clinical, basic, translational and public health research projects (Intra and Extra mural) for scientific and ethical content.
- Ensure following ethical standards related to human participants' research projects of DAPM RV Dental College.
- Function as a forum to advise the investigators in case of any ethical issues that may arise from human research participants, families or public.
- Follow updated and revised guidelines periodically, for effective functioning of the committee as and when necessary.
- The IRB/IEC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, pedodontists, radiologists etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.
- The IRB/IEC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the IRB/IEC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.

6. Composition of IRB/IEC:

- IRB/IECs shall be multidisciplinary and multisectoral in composition.
- There should be adequate representation of age and gender. Preferably 50% of the members should be non-affiliated or from outside the institution.
- The number of members in an IRB/IEC should preferably be between seven and 20 and a minimum of five members should be present to meet the quorum requirements. A small number of members drawn from a larger pool of committee members will constitute a team for review as a large committee makes it difficult in reaching consensus and in having the presence of all the members.
- The IRB/IEC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.
- The Chairperson of the committee shall be from outside the Institution.
- The Member Secretary, will belong to DAPM RVDC and shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including the general public to reflect the diversity in the society.
- The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic

scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

- The IRB/IEC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.
- A research subcommittee should review the proposal before it is referred to IRB/IEC. IRB/IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

The composition may be as follows:

- Chairperson
- Basic medical scientists
- Clinicians
- Legal expert
- Social scientist/representative of non-governmental voluntary agency
- Member Secretary
- Lay person

6.1. Quorum Requirements:

- A minimum of five members should be present in the meeting.
- The quorum should include both medical and non-medical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably a lay person should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- No decision is valid without fulfilment of the quorum.

7. Membership:

Appointing Authority: The Principal and the member Secretary shall constitute the IRB/IEC keeping in view the guidelines of SOP.

Duration: The Committee will be constituted for one term i.e., a period of 3 years, from 1st of June every year.

Renewal: Principal and Member Secretary will have the authority to continue or replace the existing members after completion of their term. At the end of the term, the appointment is automatically renewed until the membership is terminated in writing.

Replacement: A member may be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Principal and Member Secretary. During the term, the Principal and Member Secretary in consultation with the Chairperson will have the authority to replace any of the members in the event that the member

has not complied with the conditions of appointment, or on an occurrence of any event which casts a serious doubt on the integrity or ethics of the member.

7.1. Conditions of Appointment and Conflict of Interest:

- Members will be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IRB/IEC.
- Members are appointed to the IRB/IEC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.
- The duration of the membership will be 3 years.
- Members may serve for more than one term but it is desirable to have around one-third fresh members.
- A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Principal and Member Secretary.
- Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term.
- Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- Conflict of interest if any shall be declared by members of the IRB/IEC at the beginning of every meeting.

7.2. Every IRB/IEC member must:

- Provide a recent signed Curriculum Vitae and training certificates on human research protection and Good Clinical Practice (GCP) guidelines, if applicable;
- Either be trained in human research protection and/or GCP at the time of induction into the IRB/IEC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
- Be willing to undergo training or update their skills/knowledge during their tenure as an IRB/IEC member;
- Be aware of relevant guidelines and regulations;
- Read, understand, accept and follow the Conflict of Interest (COI) policy of the IRB/IEC and declare it, if applicable, at the appropriate time;
- Sign a confidentiality and conflict of interest agreement/s;
- Be willing to place her/his full name, profession and affiliation to the IRB/IEC in the public domain; and
- Be committed and understanding to the need for research and for imparting protection to research participants in research.

Resignation: If any member wishes to discontinue from the IRB/IEC he/she would be required to inform the Dean, Academics and Research in writing Members may voluntarily resign from the committee at a month's notice citing appropriate reasons and in case of internal members their membership would be considered withdrawn, if they resign from the Institute.

7.3. Types of members:

Member Type	Affiliation	Qualifications	Roles & responsibilities
Chairperson	Non-affiliated	A well-respected person from any background with prior experience of having served/ serving in an IRB/IEC	Conduct IRB/IEC meetings and be accountable for independent and efficient functioning of the committee Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations Ratify minutes of the previous meetings In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. Seek COI declarations from members and ensure quorum and fair decision making. Handle complaints against researchers, IRB/IEC members, conflict of interest issues and requests for use of IRB/IEC data, etc.
Member Secretary	Affiliated	Should be a staff member of the institution Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review Schedule IRB/IEC meetings, prepare the agenda and minutes Organize IRB/IEC documentation, communication and archiving Ensure training of IRB/IEC secretary and IRB/IEC members Ensure SOPs are updated as and when required

Member Type	Affiliation	Qualifications	Roles & responsibilities
			Ensure adherence of IRB/IEC functioning to the SOPs Prepare for and respond to audits and inspections Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IRB/IEC review. Assess the need for expedited review/ exemption from review or full review Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. Ensure quorum during the meeting and record discussions and decisions
Basic Medical Scientist(s)	Affiliated/ non-affiliated	● Non-medical or medical person with qualifications in basic medical sciences ● In case of IRB/IEC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, Severe Adverse Effects (SAE), protocol deviation, progress and completion report For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
Clinician(s)	Affiliated/ non-affiliated	Should be individual/s with recognized medical qualification, expertise and training	Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. Thorough review of protocol,

Member Type	Affiliation	Qualifications	Roles & responsibilities
			investigators brochure (if applicable) and all other protocol details and submitted documents
Legal expert/s	Affiliated/ non-affiliated	Should have a basic degree in Law from a recognized university, with experience. Desirable: Training in medical law.	Ethical review of the proposal, Informed consent form along with translation(s). MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, compliance with guidelines etc. Interpret and inform IRB/IEC members about new regulations if any
Social scientist/ philosopher/ ethicist/theologian	Affiliated/ non-affiliated	Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	Ethical review of the proposal Informed consent form along with translation (s). Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Lay person(s)	Non-affiliated	Literate person from the public or community • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community. • Is aware of the local language, cultural and moral values of the community •Desirable: involved in social and community welfare activities	Ethical review of the proposal, Informed consent form along with translation(s). Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. Serve as a patient/participant/ community representative and bring in ethical and societal concerns. Assess on societal aspects if any.

7.4. Terms of reference (TOR) for Committee members:

- The head of the institution shall appoint all IRB/IEC members, including the Chairperson.
- The appointment letter issued to all members should specify the Terms of References (TOR). The letter issued by the head of the institution should include, at the minimum, the following:
    - Role and responsibility of the member in the committee,
    - Duration of appointment,
    - Conditions of appointment
- Generally, the term of IRB/IEC membership will be for 3 years. The duration could be extended as specified in the SOPs. A defined percentage of IRB/IEC members may be changed on a regular basis.
- The IRB/IEC members may be given a reasonable honorarium for attendance at the meeting.
- Members to be appointed on the IRB/IEC should be willing to fulfil the IRB/IEC requirements.

8. Training of IRB/IEC members:

- All relevant new guidelines should be brought to the attention of the members.
- All new and existing members should attend national and international training programs/conferences/seminars/workshops etc. in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

9. Conduct of the Meeting:

The Chairperson will conduct all meetings of the IRB/IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the researchers.

10. Independent Consultants

IRB/IEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g., cancer patients, HIV/AIDS positive persons or ethnic minorities. They will not take part in the decision-making process.

11. Application Procedure

- All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
- All relevant documents should be enclosed with application.
- The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department.
- The date of the meeting will be intimated to the researchers who should be available to present the research proposal and participate in the discussion following the presentation of the research proposal.
- The decision of IRB/IEC will be communicated in writing. If revision is to be made, the revised document in the required number of copies should be submitted within a stipulated period of time as specified in the communication.

12. Schedule of IRB meetings:

Month	**Review purpose**
January	The first 3 IRB review meetings are for research projects other than PG Dissertations.
March/April	
June/July	
Sept/Oct – PG Dissertation	The Review Meeting conducted during September/October will be meant only for PG Dissertations. No other research proposals will be reviewed during this meeting.

13. Documentation:

For a thorough and complete review, all research proposals shall be submitted with the following documents: **(Annexure 1,2)**

- Title of the project
- Names of the Principal Investigator (PI) and Co-investigators (Co-PI) with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Approval of the Head of the Department.
- Protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant annexures like proforma, case report forms, questionnaires, follow–up cards, etc. to be used in the study.
- Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete

information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).

- For any drug/device trial, all relevant preclinical animal data and clinical trial data from other centers within the country/other countries, if available.
- Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
- Source of funding and Budget along with the supporting documents.
- Indemnity issues including insurance for the compensation to the participants etc.
- An undertaking to immediately report Serious Adverse Events (SAE) to IRB/IEC.
- Statement of conflicts of interest, if any.
- Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
- Any other information relevant to the study.
- Agreement to submit annual progress report and final report at the end of study.

14. Review Procedure (Annexure 3)

- Meetings of IRB/IEC shall be held on scheduled intervals as prescribed (4 times a year, the schedule for the same is circulated to all departments of the institute). Additional meetings will be held as and when necessary.
- The proposals will be sent to members at least 2 weeks in advance.
- Decisions will be taken by consensus after discussions, and voting will be done if necessary.
- PI should be available during the meeting and will be required to present the research proposal and provide clarifications if required.
- Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
- The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of the Chairperson at each page.

14.1. Call for Proposals/Submission to Research Subcommittee:

- Call for research proposals will be sent 8 weeks in advance of the IRB Meeting. 2 weeks' time will be provided for submission of research proposals.
- The proposals for IRB Review should be submitted to the IRB Committee by maximum **6 weeks before the IRB** Meeting in the prescribed format only.
    - **Four hard copies** of the research proposal and filled checklist along with **one soft copy** in PDF format with all relevant annexures should be submitted.

- Any change to be done in the research proposal after submission should be accompanied by a request letter signed by the HOD and Guide. Such changes will be permitted up to 4 weeks before the IRB Meeting.

14.2. Review Subcommittee - Roles & functions:

- Ensure timely submission of the research proposals
- Review of the submitted research proposals for scientific rigor, appropriate annexures and permissions and suggest modifications wherever needed. Clarifications may be sought with the PI and Co-Investigator if required.
- Identify and categorize proposals into those for detailed review, expedited review and certificate of exemption.
- The research subcommittee will review the submitted research proposals within 2 weeks of receiving proposals.
- In situations where the review subcommittee has recommended modifications, re-submission of the reviewed research proposal to the research subcommittee should be done within 1 week time. **(Annexure 4)**
- The second review of resubmitted research proposals by the research subcommittee should be done within 1 week of receiving the resubmitted proposal.
- The research subcommittee will circulate the reviewed research proposals to all IRB Members at least 2 weeks before the IRB Review meeting.

14.3. TimeLine of Review Process:

Call for research Proposals	8 weeks before IRB Meeting
Submission to research Subcommittee	6 weeks before IRB Meeting
Research subcommittee first review	4 weeks Before IRB Meeting (2 weeks for review)
Submission of modified research proposals to research subcommittee	3 weeks before IRB Meeting
Research Subcommittee second review	2-3 weeks before IRB Meeting (1 week for Review)
Circulation of Research proposals to IRB Members	2 weeks before IRB Meeting
IRB Review Meeting	DAY 0

15. Elements of review:

- Scientific design and conduct of the study
- Approval of appropriate scientific review committees
- Examination of predictable risks/harms
- Examination of potential benefits
- Procedure for selection of subjects in methodology including inclusion/exclusion withdrawal criteria and other issues like advertisement details.
- Management of research related injuries, adverse events.
- Compensation provisions.
- Justification of placebo in control arm, if any.
- Availability of products after study, if applicable.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and confidentiality
- Involvement of community, wherever necessary
- Plans for data analysis and reporting
- Adherence to all regulatory requirements and applicable guidelines
- Competence of investigators, research and supporting staff
- Facilities and infrastructure of study sites
- Criteria for withdrawal of patients, suspending or terminating the study.

16. Types of Review:

16.1. Exemption for review:

Proposals with less than minimal risk where there are no linked identifiers, for example;

- Research conducted on data available in the public domain for systematic reviews or meta-analysis
- Observation of public behavior when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
- Quality control and quality assurance audits in the institution
- Comparison of instructional techniques, curricula, or classroom management methods
- Consumer acceptance studies related to taste and food quality
- Public health programs by Govt agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers).

16.2. Expedited review:

Proposals that pose no more than minimal risk may undergo expedited review, for example:

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples

- Research involving clinical documentation materials that are non-identifiable (data, documents, records)
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- Minor deviations from originally approved research causing no risk or minimal risk
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee
- For multicenter research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review
- Research during emergencies and disasters (See Section 12 for further details).

16.3. Full Committee Review:

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are:

- Research involving vulnerable populations, even if the risk is minimal
- Research with minor increase over minimal risk (see Table 2.1 for further details)
- Studies involving deception of participants (see section 5.11 for further details)
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk
- Major deviations and violations in the protocol
- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment
- Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

17. Decision Making:

- Members will discuss the various issues before arriving at a consensus decision.
- A member shall withdraw from the decision-making process in case of conflict of interest and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

- Decisions will be made only in the meetings where quorum is complete.
- Only members can make a decision. The expert consultants will offer only their opinions.
- Any of the following decisions may be made by the committee –
    - Recommended
    - Recommended with modifications
    - Revision
    - Rejected
    - Certificate of exemption.
- **Certificate of exemption** may be provided to proposals which fall in the exemption from review category.
- In case of **recommended with modifications, revision and rejection**, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.
- Procedures for appeal by the researchers should be clearly defined.

18. Communicating the decision: (Annexure 5)

- Decision will be communicated by the Member Secretary in writing.
- Suggestions for modifications and reasons for rejection shall be communicated to the researcher.

19. Follow up Procedures: (Annexure 6)

- Final report should be submitted at the end of study in prescribed format including a copy of the report which has been sent to the sponsoring agency.
- Any Adverse Effects associated with interventions undertaken should be intimated immediately to IRB/IEC. The PI should submit the adverse effects reported by other centers from time to time to the Member Secretary for information to IRB/IEC along with comments if any action is required in the current study.
- Protocol deviation, if any, should be informed with adequate justifications.
- Any amendment to the protocol should be submitted for approval.
- Any new information related to the study should be communicated to IRB/IEC.
- Premature termination of study should be notified with reasons along with a summary of the data obtained so far.
- Change of investigators should be done with the approval of IRB/IEC.

20. Record Keeping and archiving:

- Curriculum Vitae (CV) of all members of IRB/IEC.
- Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
- Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.

- All study related documents (study protocols with enclosed documents, progress reports, and adverse effects) should be archived for a minimum of five years after the completion of study.
- Final report of the approved projects.

21. Administration and Management:

A full-time secretariat and space for keeping records is required for a well-functioning IRB/IEC. The members may be given reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third-party submission. There should be provision for allocating a reasonable amount of funds for smooth functioning of the IRB/IEC.

22. Special Considerations / Protection of Vulnerable Population

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 safeguards / protection and specific considerations for the IRB/IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IRB/IEC will be given in writing in unambiguous terms in such instances.

ICMR guidelines as applicable will be followed for protection of vulnerable population

23. Budget:

- A budget allocation of Rs 500-Rs 10,000(Rs 6000/- honorarium +Rs 3000/- for food +Rs 1000 for miscellaneous) shall be allocated for every research sustenance and Institutional Review Board committee meeting.
- The external review board members are eligible for a honorarium of Rs 2000/- per meeting.
- No fees shall be charged from the undergraduate and postgraduate students for the Institutional Review Board.
- An amount of Rs 8000/- (Rs 6000/- for external review board members and Rs 2000/- for miscellaneous) may be charged from external PhD students. Internal PhD students may be exempted from this. This amount shall be included in the PhD fees.

References:

1. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human participants* [Internet]. New Delhi: Indian Council of Medical Research; 2017 [cited 2020 September 9]. Available from: ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx
2. https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/ Accessed on July 23 2020
3. https://phfi.org/iiph-delhi/institutional-ethics-committee/ Accessed on July 23 2020
4. Mahuli AV, Mahuli SA, Patil S, Bhandi S. Institutional Ethics Committee Regulations and Current Updates in India. The journal of contemporary dental practice. 2017 Aug 1;18(8):738-41.
5. https://jipmer.edu.in/research/research-committees/institutional-ethics-committee/Accessed on July 23 2020

Annexure 1

PERFORMA FOR RESEARCH PROPOSAL SUBMISSION

1.	**Name of the Candidate and Address**	
2.	**Name of the Institution**	
3.	**Course of the study & subject**	
4.	**Date of admission to course**	
5.	**Title of the topic**	
6.	**Brief resume of the Intended work** 6.1 Need for the study 6.2 Aims & Objectives of Study: 6.2.1. Aim: 6.2.2. Objectives: 6.3. Review Of Literature: 6.4. Materials And Method: 6.4.1. Study Design: 6.4.2. Study Participants: 6.4.3. Study Setting & Study duration: 6.4.4. Sample Size: 6.4.5. Sampling Strategy: 6.4.6. Source Of Data: 6.4.7. Eligibility Criteria.	

	6.4.7.1. Inclusion criteria. 6.4.7.2. Exclusion criteria. 6.4.8. Methods. 6.4.9. Does the study require any investigation or interventions to be conducted on patients or other human or animals? If so, please describe briefly: 6.4.10. Has ethical clearance been obtained from your institution in case?	
7.	**References**	
8.	**Annexure**	
9.	Signature of the candidate	
10.	Remarks of the Guide	
11.	Name and designation of Guide (in block letters)	
12.	Signature of the Guide	
13.	Name and designation of Co-Guide (in block letters)	
14.	Signature of the Co Guide	
15.	Head of Department	
16.	Signature of Head of the Department	
17.	Remarks of the Chairman and Principal	
18.	Signature of the Chairman and Principal	
19.	Name of the Principal	

Annexure 2:

Application form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC) (for attachment to each copy of the proposal)

General Instructions:

- **Tick one or more options as applicable. Mention NA if not applicable.**
- **Attach additional sheets if required.**

To be filled by the Principal Investigator				**To be filled by Reviewer**
Date of Submission:				
Proposal Title:	**Name, Designation, Department & Qualifications**	**Address Tel & email Id**	**Signature**	
PI/Guide				
Co-PI/Collaborators/Student				
Budgeting:				
· **Total Budget of the Project:**				
· **Source of funding:**				
· **Sponsor Details (if Applicable):** **1. Sponsor Name/Organization:** **2. Contact Address of the sponsor:** **3. Sponsorship amount**				
1. Research Related Information				

1.1. Type of study			
□ **Multi-centric** □ **Single Centre**	□ Basic sciences □ Clinical trial □ Clinical studies □ Educational interventions □ Retrospective □ Prospective □ Qualitative □ Quantitative □ Mixed methods □ Epidemiological □ public health	□ Socio behavioural □ Cross sectional □ Case control □ Cohort □ Systematic Review □ Narrative reviews □ Concept papers □ Process documents □ Any other(specify)	
2. Methodology			
2.1. Sample size/ number of participants (as applicable)	□ Control group: □ Study group: □ NA		
2.2. Is justification for the sample size chosen mentioned	□ Yes □ No □ NA		
2.3. Duration of the study:	□ Yes □ No □ NA		
2.4. Use of biological/hazardous material.	□ Yes □ No □ NA		
2.4.1. If any biological/hazardous material is being used, kindly tick the appropriate type:	□ Use of body parts/body fluids □ Recombinant or gene therapy □ Use of pre-existing/stored/left over samples □ Use of ionizing radiation/radioisotopes Use of Infectious/biohazardous specimens. □ Proper disposal of material		

2.4.2. In case recombinant or gene therapy is being used, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	□ Yes □ No	
2.4.3. If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	□ Yes □ No	
2.5. Will any sample collected from the patients be sent outside the institution?	□ Yes □ No **Details of collaborators if sample is being sent outside the institution:**	
3. Clinical Trials: (Answer only if Applicable)		
3.1. Does the study involve use of:	□ Drug □ Device □ Herbal Remedies	
3.2. Is the drug/device/herbal remedy approved and marketed?	□ Yes □ No	
3.3.Does it involve a change in use, dosage, route of administration	□ Yes □ No **If Yes, date of Permission:**	
3.4. Has DCGI's /Any other Regulatory authority's Permission obtained?	□ Yes □ No	
3.5. Is it an Investigational New Drug?	□ Yes □ No	

3.5.1. If yes, fill the following information:	a) Investigational New Drug Number:	
	b) Investigator's brochure Number:	
	c) In vitro studies data: □ Yes □ No	
	d) Preclinical Studies done: □ Yes □ No	
	e) Clinical Study Phase: □ Phase 1 □ Phase 2 □ Phase 3 □ Phase 4	
3.6. Are you aware if this study/similar study is being done elsewhere ?	□ Yes □ No **If Yes, are the details attached?** □ Yes □ No	
4. Participant related information		
4.1.Inclusion/Exclusion Criteria given	□ Yes □ No	
4.2.Does the study involve Vulnerable subjects?	□ Yes □ No	

4.3. Please select appropriate vulnerable groups involved in your study	□ Children under 18 years □ Differently abled(mental/physical) □ Elderly □ Economically and socially disadvantaged □ Terminally ill □ Pregnant/lactating women □ Employee/students/nurses/staff □ Any Other (Specify) □ None	
5.Privacy and confidentiality		
5.1. Does the study involve?	□ Direct identifiers □ Indirect identifiers/coded □ Completely anonymized/Delinked	
5.2. Does the study involve confidential handling of data/samples by researchers?	□ Yes □ No	
5.3. Do you propose to use stored samples/data in future studies?	□ Yes □ No □ May Be	
5.3.1. If yes, explain how you might use stored material/data in the future? (in brief)		
5.4. Has the study subject been informed about publishing the results of the study/using the data for future studies?	□ Yes □ No	
6. Risks and Benefits involved in the study		
6.1. Are there any anticipated physical/social/psychological discomforts/ risk to participants?	□ Yes □ No	

6.1. If yes, categorize the level of risks :	□ Less than minimal risk □ Minimal risk □ Low risk □ High risk	
6.2. Is the risk management strategy adequately described?	□ Yes □ No	
6.3. Is there compensation for participation?	□ Yes □ No	
6.3.1. If yes, specify the amount and source of funding		
6.4. Is there a compensation for injury from/as a result of the study?	□ Yes □ No	
6.4.1. If yes, specify:		
7. Informed Consent:		
7.1. Are you seeking waiver of consent? **If Yes, specify reasons.**	□ Yes □ No	
7.2. Mention mode of consent :	□ Audio □ Video □ Signed □ verbal consent □ Parental □ Legally authorized representative	
7.3. Language used in Participant Information Sheet (PIS) and informed consent form (ICF)	□ English □ Local Language	
7.3.1. If the PIS and ICF is in English Language only, is the	□ Yes	

justification for not using local language mentioned?	☐ No		
7.4. Tick the included elements in Participant Information Sheet and Informed consent form:	☐ Understandable language ☐ Statement that study involves research ☐ Sponsor of study ☐ Purpose and procedures ☐ Risks and discomforts ☐ Benefits ☐ Compensation for participation ☐ Compensation for study related injury ☐ disclosure of research outcome	☐ Alternatives to participation ☐ Confidentiality of records ☐ contact information of PI and Member of EC ☐ Statement that consent is voluntary ☐ right to withdraw ☐ consent for future use of biological material ☐ consent for future use of research outcome for publication ☐ benefits if any on future commercialization ☐ data or sample sharing ☐ use of photographs and/or identifying data for dissemination of study	
7.5. Do you have any additional information to add in support of the application, which is not included in the form?	☐ Yes ☐ No		
If yes, Provide details			

Annexure 3:
DAPM RV DENTAL COLLEGE
Institutional Ethics Committee/Institutional Ethics Board Approval

IRB Member Review Document

Date:

- The IRB members are requested to note down their suggestions, queries and concerns regarding the research proposals in the given spaces in capitals/bold.
- The IRB members are also requested to give their final decision on the ethical review of the concerned research proposal.
- Please Note that the IRB members should not review the research proposal submitted by their respective departments. They should review all the other research proposals.
- After proper presentation and discussion of the research proposal, the IRB members may take any of the following decisions with regards to the project:

SI No.	Decision of IRB Member	Explanation
1.	**Recommended**	The research follows all guidelines, is methodologically sound and does not involve any ethical, legal or social rules/principles. It can be recommended.
2.	**Recommended with Modifications**	The research requires minor modifications in the methodology so that it does not violate any ethical, legal or social rules/principles. The modified document needs to be submitted to the IRB committee for an expedited review before an ethical clearance can be obtained from the IRB Committee.
3.	**Revision**	The research requires major modifications in its study design and methodology so that it follows all ethical, legal or social rules/principles. The revised research proposal needs to be submitted again undergo a full committee review before ethical clearance certificate can be given.
4.	**Rejected**	The research violates major ethical, legal or social rules/principles and cannot be given approval even with changes.
5.	**Certificate of exemption**	1. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques. 2. Research on curricula. 3. Research on classroom management methods-provided: a. The study meets the definition of minimal risks

		b. Adequate provisions have been made for soliciting the assent of the child. c. Adequate provisions have been made for soliciting the permission of their parents/guardians.

List of Proposals are mentioned below

SI No.	Department	Title of the research	Presenter and Guide	Suggestions/Comments/Concerns/Queries	Decision of IRB Member
1.					

Signature of the IRB Member with Date

Annexure 4: Summary Sheet to be submitted along with Revised Proposals by (date)

Name of the student and department:		
Title of the study:		
Guide:		
HOD:		
Changes made in the revised proposal		
Sl. No	**Before**	**Changes made**

Name and Signature of the PI/Student:	**Name and Signature of the Guide/Co-PI:**	**Name and Signature of the HOD:**

Annexure 5: IRB Certificate

IRB No.: **Date:**

1. Name of the Investigator/PG Student:						
1. Name of the PG Guide/ Co-investigators:						
1. Name of the Department						
1. Title of the proposal submitted for ethical clearance:						
1. Nature of the proposal submitted for ethical clearance:	**Original research**		**Review**		**Others**	
1. Type of review:	**New**		**Revised**			
1. Date of ethics committee meeting held:						
1. Date of previous review, if revised application:						

Comments:

At the Ethics Committee meeting, members of the committee reviewed the research project and study related documents and discussed the ethical issues involved. After consideration, committee has taken the following decision with respect to the research project in-principle.

For revised proposals only:

A letter to this effect was sent to you seeking certain clarifications/documents vide letter dated ……. In response to this, you have submitted required clarifications/documents vide letter dated…….. Hence the research project and study related documents are approved with respect to ethical aspects.

Clear statement of the decision reached:

The research project and study related documents are* Recommended *with respect to ethical aspects.

For IRB members:

After proper presentation and discussion of the research proposal, the IRB members may take any of the following decisions with regards to the project:

1. **Recommended** **2. Recommended with Modifications**
3. Revision **4. Rejected** **5. Certificate of Exemption**

Please Note

- Inform IEC/IRB immediately in case of any adverse events and serious adverse events.
- Inform IEC/IRB in case of any change of study procedure/site and/or investigator.
- Completed/Interim report to be submitted to IEC/IRB.
- Members of IEC/IRB have right to monitor the trial with prior intimation.

Signature of Member Secretary
IRB/IEC

Signature of Chairman
IRB/IEC

Annexure 6: Format for submission of interim report to Research Sustenance and Institutional Review Board

Name of the candidate and address:	
Guide:	
Co-Guide:	
HOD:	
Name of the institution:	
Course of Study and Subject:	
IRB Approval Number:	
Title of the study:	
Interim Report Number:	

Period for which the report is being submitted	
Start of Study Date:	
Brief Report of the Project Progress: ● Introduction ● Review of Literature ● Methodology ● Ethical issues noted during the period: ● Measures taken for the ethical issues noted during the period: ● Results ● Discussion ● Conclusion and Summary	
Progress of the study:	
Comments by previous reviewer:	
Changes Made:	

Document History Summary

A total of 23 meetings were conducted by the research subcommittee to prepare and compile the present document. A summary of the meetings is provided below:

Date	Agenda
June 2020	Provisional Registration of the IRB committee with DHR started
July 2020	Completion of Provisional IRB Registration with DHR. First draft of SOP document prepared
August 2020	Formation of Research Subcommittee Preparation of checklist for submission of research protocols Review of first draft of SOP
October 2020	Preparation of SOP for checklist for submission of research protocols modification of IRB certificate
November 2020	Draft of interim report submission form and reviewer checklist
December 2020	Modification of IRB decision document
January 2021	Finalization of all documents to be included
February 2021	Review and compilation of all documents
March 2021	Final Compilation of documents into a book format

Acknowledgments:

The development of this document has been a continuous process of more than six months. Throughout this period, we have received a lot of help and support from several individuals and we take this opportunity to thank them.

We would like to express our deepest appreciation to the management and trustees of **Rashtreeya Sikshana Samithi Trust** for always believing in us and giving us the support that was required every step of the way.

Our respected **Principal,Dr. Asha R Iyengar** has been a constant source of strength for us . She has been very encouraging about all our endeavors as a board and has at all times provided the necessary resources to carry out our work.

Our **former Principal, Dr. Dinesh M R,** currently Professor, Dept of Orthodontics and Dentofacial Orthopedics and has been instrumental in forming several committees in view of the accreditation process and he has contributed to the evolution of the Institutional review board tremendously.

Dr. K.S. Nagesh, former principal, DA Pandu Memorial RV Dental College was the founder Principal of the college. His vision for the institution has formed the baseline towards which we have been working and his vision for the institution has been inspiring. His advice as the **Chairman** of the board along with the inputs from the **members of the IRB** during the review of research proposals have been incorporated within the document.

We wish to acknowledge the **Heads of the Departments** of Oral and Maxillofacial Pathology and Oral Medicine and Radiology, **Dr. Veerendra Kumar B and Dr. Seema Patil** respectively for being very encouraging and supporting us at all times.

Lastly, we wish to acknowledge the help extended by all those who were directly or indirectly associated with the development of this document.


SOUTH WING