INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

STANDARD OPERATING PROCEDURES FOR INSTITUTIONAL ETHICS COMMITTEE(EC) OF MANUBHAI PATEL DENTAL COLLEGE & HOSPITAL,

(ADDRESS: VISHWAJYOTI ASHRAM, MUNJMAHUDA, VADODARA – 390011, GUJARAT)

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SOP VERSION: 1.0

DATE OF IMPLEMENTATION:

VERSION NUMBER: 2.0

VALID TILL: 01-08-2028

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

INDEX – LIST OF SOP's

1. Writing, Reviewing, Distributing, and Amending SOPs for Ethics Committees (ECs) 4
2. Constituting an Ethics committee (EC/EC) 5
3. Confidentiality Agreements 12
4. Conflict of Interest 13
5. Training Policy for New & Existing Members 16
6. Selection of Independent Consultants 17
7. Procedures for Allowing a Guest or Observer 18
8. Categorization of Submitted Protocols for Ethics Review 20
9. Agenda Preparation, Meeting Procedures and Minutes 22
10. Review of New Medical Device Studies 24
11. Review of Resubmitted Protocols 26
12. Review of Protocol Amendments 28
13. Continuing Review of Protocols 29
14. Review of Final reports 31
15. Review of Serious Adverse Events (SAE) reports 32
16. Review of Study Completion Reports 34
17. Management of Premature Termination, Suspension, or Discontinuation of the Study 35
18. Waiver of written or verbal/oral informed consent 37
19. Site Monitoring Visits 38
20. Dealing with Participants' Requests and Complaints 40
21. Emergency Meetings 42
22. Communication Records 44
23. Maintenance of Active study files 46
24. SOP for Archive and Retrieval of Documents 47
25. Confidentiality of Ethics Committee (EC) documents 49
26. Reviewing proposals involving vulnerable populations 50
27. Review and inspection of EC 52

Dean
Manubhai Patel Dental College
Vadodara, Gujarat.

28. Audio Visual recording of the informed consent process 53
29. References 56

INDEX – LIST OF FORMS

1. List of Forms with Purpose & Use case details 57
2. FORM – 01 – Conflict of Interest Declaration form (Annexure 1) 62
3. FORM – 02 – Confidentiality Agreement 63
4. FORM – Consent Letter by EC Members 65
5. FORM – 04 – Training certificates Submission Form 67
6. FORM – 05 – Attendance Register 69
7. FORM – 06 – Appointment Letter 71
8. FORM – 07 – EC Application/Submission Form 73
9. FORM – 08 – Request for Approval to Conduct a Study 76
10. FORM – 09 – Study Protocol Submission Checklist 80
11. FORM – 10 – Informed Consent & Participant Information Sheet 85
12. FORM – 11 – Conflict of Interest Disclosure (Investigators) 88
13. FORM – 12 – Request for Exemption/Expedited Review 91
14. FORM – 13 – Protocol Amendment Submission Form. 95
15. FORM – 14 – Progress/Continuing Review Report Form 98
16. FORM – 15 – Final Report/Study Completion Form 102
17. FORM – 16 – Serious Adverse Event (SAE) Reporting Form 106
18. FORM – 17 – Request for Waiver of Consent Form 110
19. FORM – 18 – Appeal or Complaints 113
20. FORM – 19 – Guest/Observer Request Form 116
21. FORM – 20 – Study File/Archive Log 118
22. FORM – 21 – Monitoring Visit Report 119

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Vadodara, Gujarat

INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Standard Operating Procedures (SOP) for Institutional Ethics Committee – MPDC Ethics Committee

1. Writing, Reviewing, Distributing, and Amending SOPs for Ethics Committees (ECs)

The Standard Operating Procedure (SOP) for **writing, reviewing, distributing, and amending SOPs for MPDC Ethics Committee (EC)** at Manubhai Patel Dental College & Hospital provides a formal and structured process to ensure clarity, compliance, and continual improvement in EC functions.

SOP Writing and Development

- **Responsibility:** The Member Secretary, in consultation with the Chairperson and selected EC members, leads the drafting of new SOPs or major revisions.
- **Sources:** SOPs are developed based on national/international guidelines (e.g., ICMR, ICH-GCP, Schedule Y), local regulations, and institution-specific contexts.
- **Structure:** Each SOP must follow a standardized format, typically including:
    - Purpose/scope
    - Definitions
    - Procedures
    - Roles and responsibilities
    - Documentation and forms
    - Review and revision history.

SOP Review and Approval

- **Periodic Review:** All SOPs must be reviewed periodically (at least every 2–3 years) or whenever substantial regulatory changes occur.
- **Process:**
    - Circulate draft SOPs to EC members for feedback and comments.
    - Discuss comments in an EC meeting; revise SOPs as necessary.
    - Final approval is given by the EC Chairperson and the Dean of Manubhai Patel Dental College (MPDC)
- **Documentation:** All reviews and changes must be logged, and an updated version number and effective date assigned.

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SOP Distribution

- **Internal Distribution:** Upon approval, the latest SOP copies must be provided to all EC members and secretariat staff.
- **Accessibility:** The complete and current set of SOPs should be available in the EC office and accessible for audit or review by regulatory authorities.

SOP Amendment Process

- **Initiation:** Amendments can arise from regulatory updates, institutional policy changes, audit findings, or member suggestions.
- **Drafting:** The proposed amendment is drafted and circulated to EC members for input.
- **Approval:** Amended SOPs go through the standard review and approval process before implementation.
- **Notification:** Communicate changes to all EC members and ensure previous versions are archived.

2. Constituting an Ethics committee (EC/EC)

The Ethics Committee at Manubhai Patel Dental College & Hospital, known as MPDC Ethics Committee (EC) is established as a multidisciplinary and multi-sectoral body that ensures the protection of the rights, safety, dignity, and well-being of actual or potential research participants. It serves as an independent oversight body that reviews biomedical and health research proposals to assess their ethical soundness in accordance with national and international ethical guidelines.

Name of Institutional Ethics Committee (EC) : The committee shall be known as the MPDC Ethics Committee (EC), Manubhai Patel Dental College & Hospital, Vadodara, Gujarat - 390011. This name will remain unchanged until the members choose to change it by a vote of Three-fourths of the current strength.

The **Scope** of this EC includes:

- Ensuring compliance with **ICMR National Ethical Guidelines (2017)**.
- Promoting ethically responsible and scientifically valid research.
- Protecting vulnerable populations from potential exploitation or harm.

This EC will review all studies involving human participants, biological materials, and data, particularly those falling under **biomedical and health research** as defined by the ICMR.

Ethical Basis of MPDC Ethics Committee :

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Vadodara, Gujarat.

INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

- The ECs will function independently without any interference in the review and decision making process from the Head of the Institute and administrative department of the Institute.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of research projects involving human participants.
- In evaluating protocols and ethical issues, the EC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The EC will work according to its established Standard Operating Procedures based on the Operational Guidelines for EC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005 and prevailing amendments from time to time), Indian GCP guidelines (2001) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006).
- To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
- Provide public assurance of that protection.
- The EC is established and functions in accordance with the relevant national law and regulations in force from time to time.
- The EC will review only those projects which are carried out in this institution by the staff members and students of the institution.
- The EC will also review projects which are carried out by institutional members in collaboration with other national or international institutions.

The Standard Operating Procedure (SOP) for **constituting an ethics committee (EC/EC)** at Manubhai Patel Dental College & Hospital ensures a multidisciplinary, independent, and regulatory-compliant committee as per ICMR and national guidelines.

Steps for Constituting an Ethics Committee

Authority and Initiation

- The **Head of the Institution (HOI)**, The Dean of Manubhai Patel Dental College, initiates the process and is responsible for formally appointing all EC members, including the Chairperson.
- New EC tenures or committee formations are triggered by institutional requirements, member retirement, resignation, death, or as part of regular reconstitution every 3 years.

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Vadodara, Gujarat.

INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Composition Requirements

- The EC must be **multidisciplinary and multisectoral** with 7 to 15 members, combining both medical and non-medical, scientific and non-scientific individuals.
- Mandatory member categories:
    - Chairperson (non-affiliated, preferably external)
    - Member Secretary (affiliated to the institution)
    - Basic Medical Scientist(s)
    - Clinician(s)
    - Legal Expert(s)
    - Social Scientist/NGO representative/Philosopher/Ethicist/Theologian
    - Lay person (from the community, not institution-affiliated, not in health care field).

- Adequate **gender and age representation** is essential; at least 50% should be from outside the institution where possible.

Selection and Appointment Process

- Candidates are selected for their expertise, ethical sensibility, and commitment.
- Chairperson and existing members can suggest new member names, but final selection lies with the Dean of Manubhai Patel Dental College.
- Formal appointment letters detail:
    - Term of membership
    - Roles and responsibilities
    - Terms of renewal and rotation
    - Conditions of termination and removal.
- All members must provide a recent CV, undergo orientation/training (including Good Clinical Practice), and sign confidentiality/conflict of interest declarations.

Quorum and Tenure

- Minimum five (5) members must be present for meetings, with each discipline represented for quorum (medical, non-medical, legal, social, lay, and at least one non-affiliated member).
- Tenure is typically 3 years, renewable once, to ensure continuity and fresh perspectives.

Documentation and Records

- Maintain appointment letters, signed consents, member lists (with affiliation, role), and documentation of training and COI forms.
- Changes in committee composition must be updated in records and communicated to regulatory authorities if required.

Roles & Responsibilities

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

- The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
- The EC must ensure ethical conduct of research by the investigator team.
- The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.
- Member Secretary in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
- The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
- The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- The EC should recommend appropriate compensation for research related injury, wherever required.
- The EC should carry out monitoring visits at study sites as and when needed.
- The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
- The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Composition, affiliations, qualifications, member specific roles and responsibilities of MPDC- EC

S.No.	Members of EC	Definition/description
1.	**Chairperson/Vice Chairperson** (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC 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 declaration from members and ensure quorum and fair decision making. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications- • 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 • Should be able to devote adequate time to this activity which should be protected by the institution	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC 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 EC review.

Dean
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Vadodara, Gujarat.

INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

		• Assess the need for expedited review/ exemption from review or full review. • Ensure quorum during the meeting and record discussions and decisions.
3	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC 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, SAE, protocol deviation, progress and completion report. For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4	**Clinician(s) -** Affiliated/ non-affiliated Qualifications 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, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal expert/s** Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience	• Ethical review of the proposal, ICD along with translations, 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, HMSC for international collaboration, compliance with

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	• Desirable: Training in medical law.	guidelines etc. • Interpret and inform EC members about new regulations if any
6	**Social scientist/ philosopher/ ethicist/theologian -** Affiliated/ non-affiliated -Qualifications - Should be an individual with social/ behavioural 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, ICD along with the translations. • 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.
7	**Lay person(s)** Non-affiliated Qualifications – • 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 from which the participants are to be drawn. • 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, ICD 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.

Review and Update

This SOP is reviewed every 2–3 years or as required by changes in national/regulatory guidelines.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

3. Confidentiality Agreements

The Standard Operating Procedure (SOP) for **Confidentiality Agreements** MPDC Ethics Committee (EC) establishes a comprehensive process for maintaining strict confidentiality throughout the ethical review and decision-making process.

Purpose

To ensure that all EC members, including regular, alternate members and invited experts, treat all documents, deliberations, study data, personal information, and meeting discussions as **strictly confidential**, in accordance with national guidelines and institutional policy.

Key Procedures

Signing of Confidentiality Agreements

- **At Appointment:** Every new EC member must **sign a confidentiality agreement** before being inducted as a member or participating in the review process.
- **Recurring Requirement:** Confidentiality agreements are to be renewed at intervals or whenever SOPs/policies are updated.

Scope of Confidentiality

- All information disclosed to, reviewed by, or generated within the EC—including protocols, study participant data, meeting minutes, investigator information, proprietary study documents, and committee deliberations—falls under this agreement.
- EC members are not permitted to discuss, share, or otherwise disseminate confidential information outside of official EC business, including with colleagues, friends, or family.

Documentation and Custody

- All signed confidentiality agreements are maintained in the official EC records and are **auditable** by the Head of Institution or competent authorities.
- Breach of confidentiality is considered a serious infraction and may lead to disciplinary action, including suspension or termination of EC membership.

Additional SOP Elements

- **Non-disclosure:** If any EC member feels unable to comply with confidentiality obligations (e.g., due to a conflict with institutional roles), they must **declare this prior to committee involvement** and recuse themselves from related discussions.
- **Invited Experts:** Any independent consultant or invited expert contributing to EC deliberations must also sign a confidentiality agreement prior to accessing materials or discussions.

Template/Format

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A typical confidentiality agreement includes:

- Name, designation, and affiliation of the signatory
- Scope of information to be kept confidential
- Prohibition on unauthorized copying, sharing, or retention of EC material
- A clear statement of disciplinary consequences for breaches
- Space for member's signature and date

This SOP reinforces the integrity, trust, and legal compliance of the EC by protecting sensitive data and maintaining the confidence of research participants and stakeholders at all times.

Review and Update

This SOP is reviewed every 2–3 years or as required by changes in national/regulatory guidelines.

4. Conflict of Interest

Purpose

To describe the procedure for identifying, declaring, mitigating, and managing conflicts of interest (COI) among Institutional Ethics Committee (EC) members during ethical review and decision-making processes.

Scope

This SOP applies to all EC members (regular, alternate, and invited experts) involved in the review of biomedical and health research proposals.

Definitions

Conflict of Interest (COI): A set of conditions where professional judgment concerning a primary interest (e.g., participant welfare or research validity) is, or appears to be, unduly influenced by a secondary interest (financial, personal, academic, or political).

Identifying and Declaring COI

Recognition of COI

COI may arise due to:

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- Personal relationships or close ties with investigators/co-investigators (e.g., family, departmental colleagues)
- Professional involvement as contributor/collaborator in the research, consultant, or financier
- Serving as trustee/director/manager/advisor in a funding agency or having monetary interests (salaries, honoraria, equity, intellectual property rights) in the project.

Researchers must

- Ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) that may affect their research;
- Guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and
- Prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

Declaration Process

- At the start of each EC meeting, the Chairperson/member secretary will **ask all members to declare any real, potential, or perceived COI** regarding any items on the agenda concerning research proposals, amendments, or ongoing reviews.
- Members must disclose, in writing, any such interests for themselves and immediate family members (spouse, children, dependents, or professional associates).
- **Conflict of Interest Declaration Form** must be completed and signed by the EC member before review/discussion commences. (Include annexed sample form—see below.)

In Meeting

- If a COI is identified during meeting discussions, the concerned member must declare it immediately to the Chairperson.
- The declaration and reasons must be **recorded in the minutes**.

Managing and Mitigating COI

Recusal and Participation

- Any EC member (including Chairperson) with a COI **must withdraw from the meeting** when the particular proposal is discussed, except to provide factual information if requested.
- The member's recusal status is recorded in the minutes, and he/she does not count towards quorum for that proposal's discussion or decision.[3][2]
- If the Chairperson has a COI, an acting Chairperson will be appointed for discussion/decision on the concerned item.

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Outside the Meeting

- If assigned as reviewer but with a COI, the member should promptly notify the member secretary/secretariat so review can be reassigned.

Ongoing Disclosure

- If a previously undisclosed COI is recognized after review or while monitoring an approved study, the member must promptly notify the EC for further management.

Documentation and Transparency

- All COI declarations—including recusal and management—must be recorded and maintained in EC meeting minutes.
- The declaration forms and decisions regarding management of COI should be available for audit and review as per institutional policy.

Education and Policy Review

- Regular training and sensitization of EC members on COI and related policies will be conducted at least annually.
- SOPs regarding COI will be reviewed regularly and updated per ICMR/ICMR-DBT guidelines.

Flow Chart (SOP for COI recognition and mitigation):

1. Agenda circulated → Members review for COI.
2. Declaration at start of meeting, written forms signed.
3. Member recuses if COI exists (quorum adjusted).
4. Chairperson ensures SOP is followed; Member Secretariat logs COI in minutes.
5. Ongoing: Any new COI disclosed immediately.
6. Annual education and SOP review.

This integrated approach directly reflects ICMR's mandates for dynamic, transparent, and actively communicated COI policies that safeguard the independence and objectivity of EC proceedings. ICMR National Ethical Guidelines 2017, Box 3.1 Pg.15-16

Review and Update

This SOP is reviewed every 2–3 years or as required by changes in national/regulatory guidelines.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

5. Training Policy for New & Existing Members

- An individual selected as a new member of the EC will be required to attend two meetings as an 'Observer' before being inducted as a member of the EC
- Member-secretary or an EC member will provide an introductory training to the new member.
- All EC members should undergo refresher course in Good clinical practice (GCP) annually.
- The EC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The EC may sponsor or reimburse the expenses of an EC member or prospective members for attending conference, continuing education session workshop and/ or
- All EC members should be aware of local, social and cultural norms and emerging ethical issues.

All members must undergo **initial training** at induction and **continuing education periodically**. **Training topics** required for Institutional Ethics Committee (EC) members in India as per the ICMR National Ethical Guidelines (2017) and NDCT Rules (2019):

- Protection of Human Research Participants (rights, safety, well-being, informed consent, compensation, vulnerable population safeguards)
- Ethical Principles and Guidelines (ICMR 2017, international standards like Declaration of Helsinki)
- Good Clinical Practice (GCP)
- Functions, Roles, and Responsibilities of EC Members
- Standard Operating Procedures (SOPs): development, adherence, periodic updates, review process, and access policy
- Legal and Regulatory Requirements (national and international laws, NDCT Rules 2019, obligations to CDSCO/DCGI, record-keeping, reporting requirements)
- Registration and Accreditation of EC (initial registration, renewal, notification of changes)
- Review Procedures for Research Protocols (clinical trials, amendments, adverse event reporting, timelines)

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- Documentation and Record Maintenance (essential documents, record retention—minimum 5 years post-study)
- Training Policy and Continuing Education (mandated initial and ongoing training, compliance with CLA/NDCT training programmes)

Documentation –
All trainings are required to be documented and stored in the office.

Review and Update
This SOP is reviewed every 2–3 years or as required by changes in national/regulatory guidelines.

6. Selection of Independent Consultants

Purpose
To ensure that research proposals involving specialized, complex, or emerging issues are reviewed with appropriate expertise and in accordance with national (ICMR, NDCT Rules) and institutional ethical standards.

Scope
Applies to all EC meetings where additional subject matter expertise is deemed necessary for the ethical, scientific, or legal review of research involving human participants

Definitions
Independent Consultant: An individual with recognized expertise who is *not a standing member* of the EC, invited to review and/or advise on specific issues related to a research proposal.

Procedure

Identification of Need : During proposal pre-screening or in EC meetings, the Chairperson/Member Secretary assesses if **specialized input** is required (e.g., novel methodology, vulnerable populations, specialized technology, cultural or legal contexts)

Criteria for Selection : Professional expertise relevant to the topic (e.g., medical, scientific, statistical, legal, social science, community representation).

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Vadodara, Gujarat.

Independence: Not involved in the conduct of the study or with the investigators, and not a current EC member.

No Conflict of Interest: The consultant must declare in writing that there is no real or perceived conflict of interest regarding the study under review.

Appointment Process

The EC Chairperson/Member Secretary proposes a list of suitable candidates, with CVs and credentials, to the EC for approval.

After EC consensus, a formal invitation letter is issued specifying:

- Role and scope of review
- Timeframe
- Confidentiality obligations
- Remuneration/honorarium, if any as decided by the Dean of the college.

Confidentiality and Agreement

Independent consultants must sign a **Confidentiality and Conflict of Interest Agreement** before accessing study documents or participating in discussions.

All opinions/advice provided are advisory only; decision-making authority remains with the EC.

Documentation

Consultant's credentials, signed agreements, and written report or feedback are maintained with study records and mentioned in the EC meeting minutes.

Accountability

The EC is responsible for ensuring:

- Consultants are briefed about ethical standards, institutional expectations, and confidentiality.
- Feedback from consultants is given due consideration but the decision rests with committee members only.

Review and Update

This SOP is reviewed every 2–3 years or as required by changes in national/regulatory guidelines.

7. Procedures for Allowing a Guest or Observer

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Purpose

To provide clear guidance for the attendance, conduct, and documentation of guests or observers (including trainees, regulatory authorities, auditors, accreditation representatives, prospective members, and invited experts) at EC meetings.

Scope

Applicable to all non-member individuals who attend EC meetings in any capacity other than as formal, voting committee member

Procedure

Identification and Approval

Any individual wishing to attend an EC meeting as a **guest or observer** (e.g., student, staff, external auditor, regulatory/accreditation representatives) must submit a request in writing to the EC Chairperson or Member Secretary prior to the meeting.

The Chairperson, in consultation with the Member Secretary, reviews requests and grants approval based on relevance and necessity.

Confidentiality Agreement

Before participation, **guests/observers** must sign a Confidentiality Agreement that binds them to:

- Maintain strict confidentiality regarding all meeting content, deliberations, and documentation
- Avoid retaining copies or notes of sensitive documents

Rights and Limitations

Guests/observers may attend selected portions of meetings as determined appropriate by the Chairperson.They may **not participate in discussions, express opinions, or partake in decision-making** unless specifically invited to address a particular point by the Chairperson. They have no voting rights. The Chairperson may require guests/observers to leave the meeting during confidential or sensitive discussions (e.g., proposal specific, disciplinary matters, or when conflicts of interest are discussed).

Documentation

All guests/observers must sign the attendance register for the meeting. Their name, affiliation, and reason for attendance are to be recorded in the official meeting minutes, along with a note of their status as guest/observer. Any Confidentiality Agreement signed is filed along with meeting records.

Education and Induction

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Prospective EC members must attend at least two meetings as **Observers** before formal induction, as part of the training policy.Observer-trainees are expected to adhere to all above provisions and may provide feedback about their learning experience if invited.

Accountability

Breach of confidentiality by a guest/observer may result in removal from the meeting, report to the Head of Institution, and future prohibition from attendance. Any observer or guest violating this SOP will be subject to remediation as per institutional policy.

Review

This SOP is subject to review every three years or as required following institutional or regulatory changes.

8. Categorization of Submitted Protocols for Ethics Review

Initial Full Committee Review of Research Protocols

Definition: All research protocols that require thorough ethical and scientific scrutiny—such as clinical trials, studies involving vulnerable populations, high-risk interventions, or new/unfamiliar procedures—must undergo review at a convened meeting of the full EC, with a valid quorum.

Process:

- The Member Secretary circulates study documents to all EC members at least two weeks before the meeting.
- Members read and review the protocols in advance.
- At the meeting, the PI may be invited to clarify study details, but not present during deliberation or decision-making.
- Members discuss the protocol, focusing on scientific design, risk-benefit, participant safety, and ethical issues.
- Decisions—approval, revision, or rejection—are made by consensus or voting and recorded in the minutes, along with conflict of interest declarations, recusal details, and any specific modifications required.
- **Minutes**: The Member Secretary documents all deliberations and decisions, including quorum fulfilment. Records must be signed by the Chairperson and Member Secretary and securely archived.

Expedited Review of Research Protocols

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Definition: Low-risk protocols or minor amendments (e.g., minimal-risk observational studies, administrative changes, or urgent public health research) may be reviewed by a subcommittee or designated EC members, as permitted by policy[attached_file:1, p.26].

Process:

- The Member Secretary, often in consultation with the Chairperson, identifies protocols eligible for expedited review based on risk assessment and SOP criteria.
- The review is conducted outside the scheduled full EC meeting by a subgroup or designated reviewers, who evaluate the protocol's scientific and ethical aspects.
- The expedited review outcome (approval, need for modification, or referral to full committee) is ratified at the next EC meeting and recorded in the minutes.
- **Documentation**: All actions and decisions are transparently recorded and filed with full EC records.

Exemption from Ethics Review of Research Protocols

Definition: Certain types of research may be exempt from full or expedited ethics review if they pose negligible or no risk to participants and meet specific SOP criteria (e.g., use of public datasets, educational research without identifiable information, non-invasive quality improvement activities)[attached_file:1, p.26].

Process:

- The PI submits a written request for exemption, including justification and protocol description.
- The Member Secretary or designated EC member assesses the request against SOP/ICMR exemption criteria.
- If criteria are met, exemption is granted and formally documented; otherwise, the protocol is routed for expedited or full review.
- The list of exempted studies and the rationale must be presented at the next EC meeting and documented in the minutes for transparency[attached_file:1, p.26].

Key Considerations

Risk Assessment: The choice of review category always depends on the risk posed to participants, degree of intervention, and nature of consent and confidentiality protections.

Transparency: All categorization, discussions, and decisions—regardless of pathway—must be clearly recorded in EC records and signed by the Chairperson and Member Secretary for institutional accountability and audit readiness.

Reference to Guidelines: The SOP is aligned with the ICMR National Ethical Guidelines (2017) and other applicable standards.

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Category	Pathway	Criteria/Examples	Governing SOP Section
Full Review	Convened EC meeting	Clinical trials, high/intermediate risk studies, vulnerable participants	Section 11, 12, 16, 25-26
Expedited Review	Sub-group/designee review	Minimal risk, administrative changes, urgent low-risk studies	Section 13, 26
Exemption	Desk assessment	Public datasets, anonymous non-sensitive surveys, purely educational research	Section 13, 26

9. Agenda Preparation, Meeting Procedures and Minutes

Agenda Preparation

Initiation: The **Member Secretary** is responsible for preparing the agenda for each EC meeting.

Content:

- List of protocols to be discussed, specifying whether for initial, continuing, expedited review or amendments.
- Any additional EC business: policy updates, training matters, regulatory communications, or adverse event reports.
- Status of proposals from previous meetings, pending clarifications, and follow-ups.

Circulation:

- Agenda and associated study documents are circulated to all EC members at least two weeks before the scheduled meeting to allow adequate review time.

Additional Items:

- Members may request to add issues to the agenda before the meeting.
- The finalized agenda is signed/approved by the Chairperson prior to the meeting.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Meeting Procedures

Scheduling: Meetings are held at regular, pre-decided intervals (typically monthly or as required when sufficient proposals are received).

Quorum:

- The meeting requires a quorum: minimum five members, including medical, non-medical, technical, and non-technical representation.

Chairing:

- The Chairperson leads the meeting; in their absence, the Vice-Chairperson or an elected Acting Chairperson presides.

Order of Business:

- Attendance is recorded.
- Members declare any conflicts of interest.
- Previous meeting minutes are ratified and signed.
- Proposals are presented, followed by discussion and deliberations among EC members only.
- Guest or observer attendance is limited by invitation and subject to confidentiality.
- Decisions are made by consensus or voting; only members participate in voting.
- Any urgent matters, amendments, or expedited reviews are addressed.

Documentation:

- All proceedings must be systematic, with opportunities for queries, clarification, and objective discussion.

SOP for Minutes

Preparation:

- The Member Secretary prepares detailed minutes, capturing:
  - Date, time, and venue of meeting.
  - List of attendees (with designation, including guests/observers if any), absentees and reasons (if communicated).
  - Declarations of conflicts of interest and actions taken.
  - Summary of discussions for each item on the agenda (e.g., each protocol reviewed, main points raised).
  - Decisions taken (approval, modifications, deferral, or rejection) with reasons and clear details of any conditions.
  - Quorum confirmation and voting outcomes where applicable.

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- Recusal of members (note who left and re-entered).
- Action points, follow-ups, and deadlines.

Authentication:

- Minutes must be signed by both the Chairperson and Member Secretary and retained in EC records.

Distribution:

- Ratified minutes are circulated to all EC members prior to the next meeting for review and formal approval.

Archiving:

- All minutes are archived securely for regulatory and institutional audits for at least five years post-study or as per policy.

10. Review of New Medical Device Studies

Submission Requirements

Application: The Principal Investigator (PI) submits the study proposal using the prescribed EC form, with all relevant documents attached.

Documentation: Requirements include:

- Study protocol and synopsis
- Investigator's brochure/details of the device
- Pre-clinical/animal data, safety and performance data
- Regulatory clearances, if applicable (e.g., DCGI, CDSCO approvals)
- Informed Consent Documents (in local languages)
- Patient information sheets
- Case report forms/questionnaires
- Curriculum vitae and credentials of all investigators
- Insurance/Indemnity documents, if required
- Conflict of Interest statements

Scientific and Ethical Assessment

Scientific Review: The **Basic Medical Scientist** and **Clinician** members emphasize:

- Scientific validity, research design, endpoints, methodology
- Risk-benefit analysis
- Suitability of sample size and statistical analysis plan
- Appropriateness of comparators, and management of the control arm.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Ethical Review: The full committee evaluates:

- Participant safety and well-being
- Informed consent process and documents
- Confidentiality, privacy measures
- Inclusion/exclusion/withdrawal criteria
- Compensation provisions for injury or participation
- Community impact, societal benefit, and access after the study.

Regulatory and Legal Scrutiny

Legal Expert: Reviews all necessary regulatory documents:

- Device approval from appropriate authorities (CDSCO/DCGI), if applicable
- Clinical Trial Agreement (CTA) and insurance policy
- Review for compliance with GCP, ICMR, Schedule Y, and Indian Medical Device Rules.

External Guidelines: The EC ensures congruence with ICMR, WHO, GCP, and Indian device guidelines for clinical investigations.

EC Review Procedures

Circulation and Review: Applications are circulated to all EC members at least two weeks before the meeting.

Full Committee Review: Device studies are discussed in a duly convened meeting with a statutory quorum, including medical, non-medical, and legal members.

Expert Consultation: EC may invite external technical or scientific experts for opinion when required.

Decision-Making

Consensus or Voting: After in-depth discussion, a decision is reached (approval/modification/rejection/deferral), recorded in the minutes.

Conditional Approval: If modifications are required, the investigator is informed in writing. Revised documents are reviewed either at the next meeting or through expedited review, as appropriate.

Communication and Documentation

Written Communication: The decision, including any suggestions or reasons for rejection, is conveyed in writing by the Member Secretary.

Ongoing Review: The EC may request regular progress reports, serious adverse event (SAE) reports, and final reports for ongoing monitoring.

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Record Keeping: All documents, communications, and minutes are archived as per SOP for at least 5 years after study completion.

Table: Key EC SOP Components for Medical Device Studies

Step	Responsible Entity	Major Contents/Actions
Application Submission	PI, EC Secretariat	Complete application, device data, regulatory clearances
Scientific Review	Medical Scientist, Clinician	Design, safety, risk-benefit, statistics
Ethical Review	Full EC	Consent, participant welfare, documentation, privacy
Legal/Regulatory	Legal Expert	DCGI approval, insurance, CTA, regulatory compliance
Decision-Making	Full EC	Consensus/vote, minutes, written communication to PI
Record Keeping	EC Secretariat	Archive all documents, follow-up reports

11. Review of Resubmitted Protocols

Resubmission and Documentation

- Investigator Action: After receiving conditional approval or queries from the EC, the Principal Investigator (PI) submits the revised protocol with a detailed cover letter enumerating changes/clarifications addressed.
- Required Documents: All revised study documents, including the protocol, consent forms, information sheets, investigator responses, and any newly relevant supporting material, are submitted to the EC Secretariat for official record.

Allocation of Review Pathway

- Expedited Review: For minor modifications, the resubmitted protocol may be subjected to expedited review by a subgroup of identified EC members (including at minimum one scientific and one non-scientific member), as called by the Chairperson.

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- Full Committee Review: For substantial or significant modifications, or at the discretion of the Chairperson, the resubmitted protocol is circulated to the full EC and scheduled for review at the next formal meeting (with proper quorum), ensuring all members have at least two weeks to examine the documents.

Review and Deliberation

- Assessment Focus: The reviewers verify whether the PI has satisfactorily addressed all required modifications, clarifications, or safety concerns as previously communicated.
    - Minor modifications may result in approval or requests for further revision.
    - Major or unresolved issues prompt deliberation by the entire committee for a consensus or vote.
- Consultation: If required, the EC may seek an independent expert opinion before making a final decision.

Decision-Making and Communication

- The EC may issue:
    - Approval (if all conditions are met),
    - Request for further modification, or
    - Rejection (if requirements remain unmet).
- Communication: The Member Secretary formally notifies the PI in writing of the decision, including details of any additional revisions required or final approval.

Documentation and Record-Keeping

- All correspondence, revised materials, EC discussions, decisions, and minutes are archived as per EC policy for a minimum period as stipulated for regulatory compliance.

Table: SOP for Review of Resubmitted Protocols

Step	Responsible Party	Key Actions
Resubmission	Investigator	Submit response and revised documents
Triage & Allocation	Chairperson, Secretary	Assign expedited or full committee review path

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Step	Responsible Party	Key Actions
Review and Deliberation	EC (members/subgroup)	Examine adequacy of responses; recommend outcome
Decision & Communication	EC, Secretary	Approve/request further revision/reject; inform PI
Record-Keeping	EC Secretariat	Archive all documentation and decisions

12. Review of Protocol Amendments

Submission of Amendment

- The Principal Investigator (PI) submits the amendment package including:
  - Cover letter detailing the amendment and rationale,
  - Revised protocol or affected documents (e.g., informed consent forms),
  - Summary of all changes and their implications for participants or study conduct.
- The amendment must be submitted in the prescribed format and forwarded by the Head of Department/Institution to the EC.

Screening and Processing

- The EC Secretariat checks documents for completeness and enters the amendment into the review register.
- For minor amendments not affecting patient safety, study objectives, or methodology, the Chairperson/Member Secretary may route the amendment for expedited review by selected EC members.
- Major amendments (e.g., changes in study design, eligibility criteria, risk profile, or participant documentation) are placed before the full EC at the next meeting with proper quorum.

Review and Deliberation

- Amendments are evaluated for:
  - Scientific and ethical justification,
  - Impact on participant safety, rights, and welfare.
  - Appropriateness of revised consent/processes.
  - Any new risks or risk mitigation proposals.
- The EC may request clarifications or further documentation if needed.

Decision and Communication

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- The EC may:
  - Approve the amendment,
  - Request further modifications/clarification, or
  - Reject the amendment
- The decision is communicated in writing to the PI by the Member Secretary, along with any additional instructions for implementation (e.g., re-consenting participants)

Documentation and Record-Keeping

- All amendment submissions, EC deliberations, opinions, decisions, and communications are archived following best practices for at least five years after study completion.

Amendment Review Steps Table

Step	Responsibility	Key Action/Requirement
Submit amendment	PI/Dept/Secretariat	Submit amendment and all supporting documents
Assign for review	Chair/Secretary	Route for expedited (minor) or full (major) EC review path
EC review	EC/assigned members	Assess scientific, ethical, and risk implications
Decision/communication	EC, Member Secretary	Approve, modify, or reject; formal notification to investigator
Archive documentation	EC Secretariat	Keep comprehensive records of all amendment-related activities

13. Continuing Review of Protocols

Scheduled Interval Reviews

- The EC conducts continuing reviews at least annually, or more frequently as determined by the risk level of the study or as required by regulations.
- The Investigator is responsible for submitting progress reports at the prescribed intervals, which include:
  - Summary of study progress and any changes since prior review,
  - Enrolment and withdrawal numbers,
  - Updated risk/benefit assessment,

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- Reports on adverse events, protocol deviations, and safety data.

EC Review Process

- The submitted documents are distributed to EC members for review prior to the scheduled meeting.
- EC evaluates:
  - Ongoing scientific validity and ethics,
  - Compliance with approved protocol,
  - Continued appropriateness of participant protection measures,
  - Any new information that may impact risk/benefit assessment,
  - Adherence to regulatory and institutional requirements.
- The review includes scrutiny of Serious Adverse Events (SAEs), protocol deviations, and any amendments made since the last approval.

Outcome and Actions

- The EC may issue a decision to:
  - Continue the study as approved,
  - Request modifications to enhance participant safety and ethical compliance,
  - Suspend or terminate the study (if risks outweigh benefits or for non-compliance)
- The EC communicates its decision in writing to the investigator, stipulating requirements (if any) for future reviews and ongoing reporting.

Documentation and Archiving

- All continuing review submissions, EC decisions, and related correspondence are stored as part of the official protocol record for a minimum of five years post-study completion.

Table: Continuing Review SOP Steps

Step	Responsibility	Key Requirements/Actions
Submit progress report	Investigator	Annual or more frequent, with progress and safety data
Review of documents	EC, all members	Assess risk/benefit, compliance, new info, protocol adherence
EC decision	EC	Approve continuation, request changes, suspend, or terminate

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Step	Responsibility	Key Requirements/Actions
Communicate outcome	EC Secretary	Written notification to investigator
Documentation/archiving	EC Secretariat	Keep all records for at least 5 years after completion

14. Review of Final reports

The SOP for review of final reports by the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital ensures that the completion of each research study is ethically, scientifically, and administratively validated, with particular focus on participant safety and data integrity. Review of Final Reports :

Investigator's Submission

- The Principal Investigator (PI) must submit a final report to the EC at the conclusion of the study, including:
  - Summary of study results,
  - Details of any adverse events or protocol deviations,
  - Confirmation of participant follow-up,
  - Statements on data confidentiality and storage.

EC Review Procedure

- The final report is reviewed during a convened EC meeting.
- EC members:
  - Verify that the study was conducted in accordance with the approved protocol,
  - Review participant safety outcomes and management of adverse events,
  - Assess adherence to ethical principles throughout the study,
  - Examine handling of protocol deviations or amendments,
  - Ensure that data privacy and confidentiality have been maintained.

Decision and Communication

- The EC may:
  - Accept the final report and formally close the project,
  - Request clarifications or additional documents if concerns arise,
  - Recommend further actions if serious ethical or safety issues are found
- The outcome and any required actions are communicated in writing to the PI.

Archiving

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- All final reports, EC review documentation, and related communications are archived by the EC secretariat for a minimum of five years after study completion.

Key Steps Table

Step	Responsibility	Core Actions
Submit final report	Principal Investigator	Results, adverse events, confidentiality
EC review	EC members	Protocol adherence, safety, ethical conduct
EC decision	EC	Accept, query, or request further action
Communication	EC Secretary	Written notification of EC decision
Archiving	EC Secretariat	Maintain all documents 5+ years

15.Review of Serious Adverse Events (SAE) reports

The SOP for review of Serious Adverse Events (SAE) reports by the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital mandates swift, thorough, and independent assessment to ensure participant safety and regulatory compliance.

SOP for Review of SAE Reports

Investigator's Responsibility

- Investigators must report all Serious Adverse Events (SAEs) immediately to the EC, following national regulatory timelines and requirements.
- Reports must include a detailed description of the SAE, actions taken, outcomes, and any protocol amendments or risk mitigation measures.

EC Review Process

- On receiving an SAE report, the EC:
  - Reviews the event during its scheduled or, if needed, an unscheduled meeting.
  - Evaluates the nature, severity, causality, and impact of the SAE on study participants.
  - Determines whether study continuation is ethically acceptable or if protocol modifications or temporary suspension are necessary.

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- May consult with independent subject experts if further clinical or technical input is required.
- Ensures that all SAE discussions and actions taken are thoroughly documented in EC minutes.

EC Decision and Actions

- The EC may:
  - Recommend continuation with or without modifications,
  - Require additional monitoring or safeguards,
  - Temporarily suspend or terminate the study in cases of unacceptable risk.
- Communicates the decision promptly and in writing to the Investigator and other relevant stakeholders (e.g., regulatory authorities, sponsor).

Documentation and Archiving

- All SAE reports, EC reviews, correspondence, and resulting actions are securely archived for at least five years post-study completion.

Steps Table: SAE Report Review

Step	Responsibility	Key Actions
Report SAE	Principal Investigator	Submit detailed SAE report to EC swiftly
EC review	EC members	Assess seriousness, causality, and recommend actions
Decision and communication	EC Secretary	Inform PI of decision and regulatory requirements
Documentation/archiving	EC Secretariat	Archive all SAE and review materials (≥5 years)

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

16. Review of Study Completion Reports

The SOP for review of study completion reports by the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital outlines a structured process to ensure ethical compliance, participant safety, and completeness of all approved research studies before formal closure.

SOP for Review of Study Completion Reports

Investigator's Submission

- The Principal Investigator (PI) must submit a study completion report to the EC after all study procedures and follow-up are finished.
- The report must include:
  - Final study results and data summary,
  - Details of protocol adherence and any deviations,
  - Adverse events (including SAEs) and their management,
  - Status of participant safety and confidentiality,
  - Confirmation that all regulatory and ethical requirements have been met.

EC Review Process

- The study completion report is reviewed by EC members at a convened meeting.
- The EC assesses:
  - Whether the study was conducted in accordance with the originally approved protocol,
  - Proper management and reporting of adverse events,
  - Complete and ethical handling of all data,
  - Any remaining concerns regarding participant safety or rights.
- The committee may request clarification or additional information if needed.

Decision and Communication

- The EC may:
  - Accept the completion report and formally close the study,
  - Require corrective actions or further documentation,
  - Raise concerns if ethical or regulatory noncompliance is identified.
- The final decision is communicated in writing to the investigator.

Documentation and Archiving

- All study completion reports, review notes, correspondence, and EC decisions are archived securely for a minimum of five years post-study completion.

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Key Steps Table

Step	Responsibility	Actions
Submit report	Principal Investigator	Completion details, results, safety summary
Review by EC	EC Members	Assess adherence, safety, ethics, documentation
Decision & communication	EC Secretary	Written notification of EC judgment
Archiving	EC Secretariat	Maintain all documents ≥ 5 years post study

17. Management of Premature Termination, Suspension, or Discontinuation of the Study

The SOP for Management of Premature Termination, Suspension, or Discontinuation of a Study by the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital defines a formal, ethical, and transparent process to ensure participant safety, proper documentation, and regulatory compliance in such events.

SOP for Management of Premature Termination, Suspension, or Discontinuation

Notification by Investigator

- The Principal Investigator (PI) must immediately inform the EC in writing if a study is prematurely terminated, suspended (temporarily stopped), or discontinued before the planned completion.
- The notification should detail:
  - The reason(s) for the action (safety concerns, protocol deviations, sponsor directives, or regulatory order),
  - A summary of data collected up to the point of termination,
  - Measures taken to ensure continued safety and care of study participants.

EC Review and Action

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- The EC reviews the report at a convened meeting, focusing on:
  - Ethical and safety implications of the termination or suspension,
  - Adequacy of participant notification and follow-up,
  - Whether protocol deviations or unanticipated problems are involved.
- The EC may request further details or corrective action if concerns remain.

Communication to Stakeholders

- The EC's decision and recommendations are formally communicated to the PI, relevant regulatory authorities, sponsors, and, if required, affected participants.
- The PI must provide information to participants regarding ongoing care and any additional risks related to their participation or study discontinuation.

Final Study Documentation

- The PI submits a summary report, including:
  - Status and disposition of all enrolled participants,
  - Safety data and adverse event summaries,
  - Any compensation or care arrangements.
- The EC archives all notifications, review notes, correspondence, and decisions for a minimum of five years.

Key Steps Table

Step	Responsibility	Action Summary
Notification to EC	Principal Investigator	Written notice with reasons, data summary, participant care
Review and recommendations	EC	Convened review, requests clarification if needed
Communication to stakeholders	EC & PI	Written communication to PI, regulators, participants
Final documentation/archiving	PI & EC Secretariat	Submit final report; EC archives all correspondence

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18. Waiver of written or verbal/oral informed consent

A waiver of written or verbal/oral informed consent is permitted by the Institutional Ethics Committee (EC) in specific, justified situations, provided all regulatory and ethical criteria are strictly met. The SOP for granting such a waiver aligns with ICMR National Ethical Guidelines and international standards.

SOP for Waiver of Written or Verbal/Oral Informed Consent

Conditions for Waiver

A waiver may be considered only if ALL of the following are met:

- The research involves minimal risk to participants.
- The waiver will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver.
- Wherever appropriate, participants will be provided with additional pertinent information after participation.
- Specific cases:
    - Research involves de-identified or anonymized data/samples.
    - Large-scale retrospective chart reviews with no direct participant contact.
    - Public health surveillance or studies where general consent is not feasible.
    - Emergency/disaster situations where consent cannot reasonably be obtained.

Application Process

- Investigators must explicitly request a waiver in the submission to EC, stating clear scientific and ethical justification.
- The protocol must detail:
    - Why obtaining informed consent is not practicable,
    - How risk is minimized and confidentiality is protected,
    - Relevant laws, guidelines, or policies supporting the waiver.

EC Review and Decision

- The full EC reviews each waiver request.
- The decision is based on:
    - Scientific, ethical, and legal basis for the waiver,
    - Assessment of risk level and participant protection,
    - Provisions for post-participation information, if needed.
- No waiver is granted in studies involving more than minimal risk, sensitive/personal information with possible harm, or research with vulnerable groups unless specifically justified and safeguarded.

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Documentation

- Details of the waiver (justification, regulatory references, EC discretionary comments) are recorded in EC meeting minutes.
- If granted, the waiver—including its scope and conditions—is conveyed in writing to the investigator.
- The EC retains all supporting documents and decisions for audit and record-keeping.

Reference Table: Key Steps

Step	Responsibility	Details
Application	Investigator	Provides written request for waiver with justification
Review	EC	Full committee review; assesses risk, legal, and ethical grounds
Decision	EC	Documents the decision and rationale in minutes; states approval or rejection, conditions if any
Notification	EC → Investigator	Provides written approval/rejection and any special safeguards required

19. Site Monitoring Visits

Purpose

The purpose of site monitoring visits is to ensure the rights, safety, dignity, and well-being of research participants and monitor compliance with approved protocols, regulatory requirements, and ethical standards.

Responsibilities

- The EC is responsible for planning, executing, and documenting site monitoring visits as part of both initial and continuing review.
- Monitoring is especially important for studies involving vulnerable populations or higher risk protocols.

Scope

- All research studies involving human participants, as approved by the EC, are subject to monitoring.

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- Monitoring may be conducted for ongoing studies, in response to protocol violations, adverse event reports, or at random.

Types of Monitoring Visits

- Routine Visits: Scheduled at periodic intervals (at least once a year or as deemed necessary).
- For-Cause Visits: In response to concerns about protocol deviations, participant safety or complaints.
- Close-Out Visits: At or near study completion to verify final data and ensure proper closure procedures.

Procedures

Planning the Visit

- The EC selects studies/sites for monitoring based on risk assessment.
- The Member Secretary notifies the Principal Investigator (PI) regarding the timing and purpose of the visit, except for surprise/for-cause visits.
- A team (can include EC members, independent experts, or designated staff) is appointed to conduct the visit.

Conducting the Visit

- The monitoring team reviews:
  - Approved study protocol and consent documents.
  - Site compliance with GCP/ICMR/National guidelines.
  - Participant records, signed consent forms, and data integrity.
  - Procedures for privacy, confidentiality and reporting of adverse events.
  - Any protocol violations or deviations and the response to them.
- The team may interview investigators, coordinators, and (with consent) participants.

Reporting

- Observations/findings are documented in a monitoring report.
- The PI is provided with feedback and asked to respond or address findings.
- The EC discusses the report at a convened meeting, records the findings in the minutes, and recommends corrective actions as necessary.

Follow-Up

- The EC tracks resolution of any issues/deficiencies until closure.
- Repeat visits may be planned if concerns are not resolved.

Documentation and Record-Keeping

- All monitoring reports, correspondence, and EC decisions are filed as part of the official study record.

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- Records are retained for at least five years post-study or as per national requirements.

Table: Key Steps in Site Monitoring

Stage	Responsible	Activities/Documentation
Planning	EC Secretariat	Selection of site/study, notification of PI
Conduct Visit	EC/Delegates	Review procedures, records, interviews
Reporting	Monitoring Team	Written site visit report, PI feedback
Follow-Up	EC	Ensure corrective actions, possible repeat visit
Records	EC Secretariat	All reports/minutes filed and archived

20. Dealing with Participants' Requests and Complaints

The Standard Operating Procedure (SOP) for dealing with participants' requests and complaints ensures that every concern raised by a participant in a research study is addressed promptly, confidentially, and fairly by the Institutional Ethics Committee (EC). This upholds ethical standards and protects the rights, safety, and dignity of all research participants.

Purpose

To provide a systematic process for receiving, investigating, addressing, and documenting requests or complaints by research participants regarding their participation, rights, welfare, or ethical concerns in EC-approved studies.

Policy and Principles

- Participants have the right to ask questions, request information, or lodge complaints about any aspect of the research in which they are involved.
- The EC will treat all submissions with confidentiality, respect, and in a non-retaliatory manner.
- All requests and complaints are handled without delay and with full documentation.

Procedure

Receiving Requests/Complaints

- Participants may submit requests or complaints verbally, in writing, or electronically.

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- The EC Secretariat receives and records the request or complaint, ensuring the identity and nature of the concern are documented securely.

Acknowledge and Record

- The Secretariat formally acknowledges receipt within a reasonable timeframe.
- The request/complaint is entered into the EC complaint log for tracking.

Preliminary Review

- The EC Member Secretary initially reviews the request/complaint to assess seriousness and determine if immediate action is needed (e.g., if there are safety concerns).
- For minor requests, the Secretariat may directly provide information or clarification.

Investigation

- For complaints involving protocol deviation, adverse events, or alleged misconduct:
  - The EC notifies the Principal Investigator (PI) and, if appropriate, the sponsor.
  - The EC may conduct interviews, request documents, or perform a site visit if needed.
  - If required, an independent subcommittee investigates complex or sensitive cases.
- All actions and findings are documented in the minutes.

Resolution and Communication

- The EC deliberates on findings and recommends corrective actions where necessary.
- The Secretariat communicates the outcome and any recommended remedies to the participant in writing.
- In cases involving study amendments or disciplinary action, the EC notifies relevant authorities and updates the participant accordingly.

Follow-Up and Closure

- The EC ensures the participant's concern is resolved to the extent possible and that remedial actions are completed.
- The complaint is marked as closed only after confirmation of adequate resolution.

Documentation and Recordkeeping

- All correspondence, reports, and EC deliberations are securely archived for reference and audit.
- The entire process, from receipt to closure, is documented to ensure accountability and transparency.

Table: Steps in Managing a Participant Complaint

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Stage	Responsible	Action/Documentation
Receipt	Secretariat	Log details, acknowledge participant
Preliminary	Member Secretary	Review and triage, record actions
Investigation	EC/Subcommittee	Investigate, document findings
Resolution	EC	Decide action, communicate outcome
Follow-up	Secretariat	Confirm satisfaction, close complaint
Recordkeeping	Secretariat	Archive all relevant documentation

21. Emergency Meetings

The SOP for Emergency Meetings of the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital provides a standardized process to address urgent ethical, safety, or protocol concerns that cannot wait for the next scheduled meeting.

Purpose

To outline the process for convening, conducting, and documenting emergency EC meetings when urgent situations demand immediate attention, such as serious adverse events, protocol violations, participant safety threats, regulatory queries, or issues requiring rapid decision-making.

Scope

- Applies to all urgent EC business that cannot be delayed until a regular meeting.
- May involve urgent review of amendments, unanticipated serious adverse events (SAE), suspension/termination requests, or external directives.

Process

Trigger and Initiation

- The need for an emergency meeting can be triggered by:
  - Notification of a SAE or participant safety concern.
  - Protocol deviations needing urgent EC guidance.
  - Requests from investigators, sponsors, institution, or regulators.

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- Any EC member, the Member Secretary, or the Chairperson may call for an emergency meeting upon assessing the urgency.

Notification and Convening

- All EC members must be notified at the earliest opportunity (phone, email, written).
- Notice should state:
  - Reason for emergency convening.
  - Agenda of business to be discussed.
  - Date, time, and location (in-person or virtual).
- Minimal required documents should be circulated promptly for review.

Quorum and Participation

- Emergency meetings must meet minimum quorum requirements as per SOP:
  - At least five members, representing medical, non-medical, technical, and lay categories.
  - Representation of non-affiliated and lay persons preferred.
- If full quorum cannot be achieved, participating members must ensure balanced decision-making, and reasons for exceptions must be recorded.

Deliberation and Decision-Making

- The Chairperson (or her/his delegate) moderates the meeting.
- Discussion is focused strictly on the urgent issues listed in the agenda.
- The EC may invite subject matter experts for input but only members may vote on decisions.
- Decisions are ideally by consensus; if not possible, by simple majority (votes recorded).

Documentation

- All discussions, procedures, and decisions are documented in a dedicated emergency meeting minutes, listing:
  - Attendance and quorum status.
  - Issues discussed.
  - Rationale for decisions taken.
  - Any timeline or follow-up action required.
- Minutes are signed by the Chairperson and Member Secretary and communicated to relevant stakeholders (investigators, sponsor, institution)

Follow-Up

- Actions arising from emergency decisions are tracked by the EC secretariat.

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- If needed, outcomes are reviewed at the next regular EC meeting for ratification or further deliberation.

Table: Emergency Meeting Workflow

Stage	Responsible	Key Actions	Documentation
Initiation	Chair/Secretary	Identify urgency, call meeting	Notification record
Notification	Secretariat	Alert EC members, share agenda/docs	Circulation log
Meeting	Chair & Members	Quorum, focused discussion	Emergency minutes
Decision	Voting members	Approve, reject, defer	Recorded in minutes
Follow-up	Secretariat	Communicate/track actions	Action log, future EC records

22. Communication Records

Purpose

To establish a procedure for the systematic documentation, management, and archiving of all communications related to EC activities, including correspondence with investigators, institutional authorities, regulators, sponsors, participants, and EC members.

Scope

- Applies to all forms of communication—letters, emails, meeting minutes, decisions, reports, notifications, and queries—connected to ethical review and oversight by the EC.
- Covers both incoming and outgoing communication.

Process

Creation and Receipt of Communication

- All official communications, including study submissions, queries, decision letters, notifications, amendment requests, and responses, should be addressed to or routed via the EC Secretariat.

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Registration and Log Maintenance

Each communication (received or dispatched) is:

- Entered in the EC correspondence log or register, which records the date, sender/recipient, subject, and action taken.
- Given a unique serial/reference number for traceability.

Filing and Documentation

- A copy of every communication—whether hard copy or electronic—is filed in the relevant project/study file or general correspondence file.
- Electronic communications are printed or digitally saved in secure, backed-up EC folders.

Retention and Accessibility

- All communication records are retained in the EC office for at least five years after project closure or as per institutional/national guidelines.
- Access to communication records is limited to authorized EC personnel and is provided to regulatory authorities or auditors upon request.
- Periodic back-up of digital records is ensured.

Security and Confidentiality

- Secure storage—locked cabinets for physical files and password-protected drives for digital records—is maintained to safeguard confidentiality.
- Only EC-authorized persons may handle or release these records.

Destruction of Records

- At the end of the retention period, records are destroyed as per institutional policy, ensuring confidentiality (shredding/purging), and this process is documented.

Key Elements Included in Communication Records

- Study submissions and amendments
- Approval, query, and rejection letters
- Reports and notifications (SAEs, protocol deviations, final reports)
- Correspondence with investigators, institutional heads, sponsors, regulators, and participants
- Meeting notices, agendas, and minutes
- Records of any complaints, issues, or appeal.

Responsibility

The EC Secretariat is responsible for executing and monitoring all steps outlined above, and for managing regular audits of communication records for completeness and integrity.

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23. Maintenance of Active study files

The Standard Operating Procedure (SOP) for maintenance of active study files by the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital ensures that all documentation related to ongoing (active) research studies is systematically organized, updated, and securely preserved throughout the duration of the study and beyond.

Purpose

To establish a standardized process for maintaining comprehensive, up-to-date, and secure files for each active research study under EC oversight.

Scope

- Applies to all research projects approved by the EC and ongoing at the institution.
- Covers all study-related documents and communications received or generated throughout the study lifecycle.

Procedure

File Creation

- Upon EC approval, a dedicated study file is opened for each project in the EC office.
- Both physical (paper) and/or electronic files may be maintained per institutional policy.

Contents of Active Study Files - Each study file should include, at minimum, the following documents

- Final approved protocol and all amendments
- EC application and approval letters
- Investigator brochure, where applicable
- Informed Consent Documents (all languages/versions in use)
- Curriculum Vitae and GCP/training certificates of investigators
- Regulatory approvals/clearances, if applicable
- Study-related correspondence (with investigators, sponsors, regulators)
- Progress reports (annual or otherwise), site visit reports, and serious adverse event (SAE) notifications with EC actions/decisions
- Protocol deviations/violations and related communications
- Amendment requests and EC determinations
- Monitoring, audit, and closure reports
- Any complaints or participant communications
- Other relevant documentation (budget/insurance, publications, etc.)

File Updates and Access

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- The EC Secretariat is responsible for ensuring that all new/updated documentation is promptly filed and organized chronologically.
- Files are reviewed and updated at every significant study event: approval, progress review, receipt of reports, amendments, SAEs, or new correspondence.

Security and Confidentiality

- Files are maintained in a secure, access-restricted environment (locked cabinets for physical files; password protection for digital files)
- Access to the files is granted only to authorized EC personnel or regulatory/audit officials.

5. Record Integrity

- No original documents are removed; if necessary, copies are made and movements are logged.
- Any corrections or additions are dated, initiated, and explained where required.

File Retention and Archiving

- Active study files are maintained during the full life of the project.
- Upon study closure (completion or termination), the file is updated with closure/termination reports and then archived for a minimum regulatory-mandated period, typically five years post-closure, unless otherwise defined by institutional/national policies.

- Files should be readily available for periodic audits by internal, regulatory, or accreditation bodies.

Responsibility

The EC Member Secretary and Secretariat are collectively responsible for creating, maintaining, updating, safeguarding, and eventually archiving all active study files.

The Standard Operating Procedure (SOP) for **Archive and Retrieval of Documents** in the Institutional Ethics Committee (EC) at Manubhai Patel Dental College & Hospital outlines the systematic process for securely storing, archiving, and retrieving EC documents, ensuring compliance, confidentiality, and ease of access for audits or reference.

24. SOP for Archive and Retrieval of Documents

Purpose

To ensure the secure, confidential, and organized archiving of all EC records and to establish a clear procedure for the timely retrieval of documents when required by authorized individuals.

Scope

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- Applies to all documents produced or received by the EC, including meeting minutes, protocols, reports, correspondence, approvals, SAE reports, and related regulatory documents.
- Includes both physical and electronic records of studies and EC operations[attached_file:1, p.33].

Procedure

Archiving Process

- Upon completion (closure or termination) of a study, the active study file is updated and moved to the EC archive.
- The archive includes:
    - Copies of all study protocols with original documents and enclosures.
    - Progress reports, SAE reports, and correspondence.
    - Minutes of all EC meetings signed by the Chairperson.
    - Regulatory and national/international guidelines.
    - Curriculum vitae of EC members.
    - Documents are stored in a secure, access-restricted environment (locked cabinets for physical files; password-protected systems for digital files).
    - Files are labeled with study identifiers, dates, and closure status for easy tracking.

Retention Period

Documents are retained for at least **five years after the completion or closure of the research project** or as mandated by national/institutional policy. The retention period may be extended for regulatory or legal requirements.

Confidentiality and Security

Only authorized EC personnel or regulatory authorities may access archived records. Logs of retrieval and return of documents are maintained to track movement and prevent unauthorized removal or loss.

Destruction of records after the retention period is performed securely (e.g., shredding or digital purging) and is documented.

Document Retrieval Procedure

Requests for retrieval of archived documents should be made in writing to the EC Member Secretary, specifying the purpose and document(s) required. The Member Secretary or designated staff locates, logs, and provides the document(s) only to authorized personnel. After use, documents are promptly returned and re-archived, with all movements recorded in the archive log. Temporary removals for audits, inspections, or regulatory review must be tracked and promptly restored.

Periodic Review and Audit

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Regular checks are conducted to ensure archival integrity, completeness, and security.Compliance with the SOP is reviewed during internal or external audits.

Responsibility

The **EC Secretariat/Member Secretary** is responsible for the archiving, retrieval, security, and final disposition of all EC documents, ensuring a robust documentation trail for regulatory and ethical oversight.

25. Confidentiality of Ethics Committee (EC) documents

The Standard Operating Procedure (SOP) for maintaining confidentiality of Ethics Committee (EC) documents at Manubhai Patel Dental College & Hospital establishes robust measures to protect the privacy of all information related to research proposals, participant data, deliberations, and documentation handled by the Institutional Ethics Committee (EC).

Purpose

To ensure that all records, deliberations, and sensitive information managed by the EC/EC remain confidential, accessible only to authorized individuals, and are not disclosed to unauthorized parties under any circumstances.

Scope

- Applies to all hard copy and electronic documents related to EC functions, including research proposals, meeting minutes, correspondence, participant records, and review materials.
- Covers all EC members, secretariat, and any consultants or invited experts.

Confidentiality Measures

Access Restriction

- Only EC members and designated secretariat staff may access confidential documents and meeting deliberations.
- Physical documents are stored in locked cabinets, and digital records are password-protected and access-limited.

Confidentiality Agreements

- All EC members and associated personnel must sign a Confidentiality Agreement upon appointment, affirming their responsibility to safeguard all privileged information.
- Confidentiality extends to all documents, discussions during meetings, and any participant or protocol data reviewed.

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Handling and Storage

- Documents are handled with care to prevent unauthorized viewing, copying, or dissemination.
- At the end of meetings, all materials remain within the EC's secure custody.

Disclosures and Communications

- Study documents or discussions are not disclosed outside the EC except as required for regulatory review, audits, or as per applicable law.
- Any external requests for information must be reviewed and approved by the Chairperson or Member Secretary.

Documentation of Decisions

- Minutes of meetings, correspondence, and review notes are considered confidential and are labeled as such.
- All discussions, especially regarding proprietary, participant, or research-sensitive data, are not shared with unauthorized persons.

Retention and Archiving

- Confidential documents are archived as per SOP and retained in secure locations with strictly limited access throughout their retention period.

Breach Management

- Any suspected or actual breach of confidentiality must be immediately reported to the EC Chairperson or Member Secretary for prompt investigation and corrective action.

Responsibilities

- All EC members and the Secretariat: Must read, understand, and abide by the confidentiality policy and SOPs, ensuring strict protection of all sensitive information throughout their tenure and beyond.

26. Reviewing proposals involving vulnerable populations

The SOP for reviewing proposals involving vulnerable populations at Manubhai Patel Dental College & Hospital EC requires stringent, documented procedures in line with ICMR National Ethical Guidelines (2017) to ensure rigorous protection of participant rights and safety.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Purpose

To ensure that all research proposals involving vulnerable individuals or groups receive enhanced ethical scrutiny, special safeguards, and persistent monitoring during both initial and continuing review stages.

Definition of Vulnerable Populations

Vulnerable populations include, but are not limited to:

- Children and minors
- Pregnant women
- Prisoners
- Persons with mental illness or cognitive impairment
- Persons with disabilities
- Economically or socially disadvantaged groups
- Any group at increased risk of unintended harm or exploitation in research.

Review Process

Full Committee Review: Protocols involving vulnerable populations must be reviewed by the full EC/EC in a formal meeting; expedited or delegated review is not permitted for such cases.

Quorum Requirement: The meeting must have full quorum, including representation from a lay person and, if possible, a member providing the perspective of the vulnerable population involved.

Scientific and Ethical Justification: The EC must require a clear rationale for inclusion of the vulnerable group, along with demonstration of scientific necessity and minimization of specific risks.

Enhanced Safeguards: Additional protections should be described, such as:

- Obtaining consent from Legally Authorized Representatives (LAR) where direct consent is not possible
- More frequent monitoring or site visits
- Special measures to ensure voluntariness and absence of coercion.

Deliberations and Decision-Making: Decisions are made by consensus or voting during the meeting, and recorded in minutes. Any concerns, recommendations for revisions, or additional safeguards required must be clearly documented.

- Ongoing Oversight: Continuing review must pay special attention to actual implementation of safeguards, reporting of adverse events, and subject well-being.

Key Elements for EC Consideration

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- Justification for including or excluding vulnerable populations is critically assessed
- Clear assessment of risk-benefit ratio and appropriateness of proposed safeguards
- Ensure conflicts of interest do not compromise participant welfare
- Recommendations for risk minimization or additional protective measures mandated when required
- The EC may recommend inclusion of a representative from the specific vulnerable population during deliberations, especially for context-specific issues.

Documentation and Transparency

- The entire review process and EC decisions—including all safeguards, dissenting opinions, and special requirements—must be clearly minuted and securely archived
- Researchers must be informed in writing of any additional obligations or conditions of approval specific to the vulnerable group in question.

27. Review and inspection of EC

The Standard Operating Procedure (SOP) for review and inspection of the Ethics Committee (EC) at Manubhai Patel Dental College & Hospital outlines structured processes for both the ethical review of research proposals and compliance inspections to ensure accountability and adherence to regulatory standards.

SOP for Review of Proposals

Initial & Continuing Review: All research proposals are subject to a thorough initial review, including scientific, ethical, medical, and social aspects, followed by periodic continuing review throughout the life of the project.

Independent & Multidisciplinary Evaluation: The EC conducts reviews independently, ensuring multi-sectoral representation—including medical, non-medical, legal, scientific, and lay members—for broad-based perspective and unbiased decision-making.

Meeting & Quorum: Reviews are conducted in scheduled meetings, requiring a minimum quorum (generally at least 5 members with both medical and non-medical representation), as documented in the SOP.

Submission Requirements: Investigators must submit detailed protocols with all relevant documents, including informed consent forms, investigator CVs, participant materials, regulatory approvals, conflict of interest statements, and data privacy safeguards.

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Review Procedures:

- Reviewers receive proposals at least two weeks in advance.
- Decisions are by consensus or majority when needed, and only members (not outside consultants) may vote.
- Minutes of all meetings are documented and approved by the Chairperson before issuance to stakeholders.
- Decision Communication: The outcome—approval, requirement for modification, or rejection—is communicated in writing to investigators, with reasons for decisions clearly documented.

Ongoing Monitoring: Progress reports, adverse events, protocol deviations, and final reports are reviewed regularly. Site inspections may be conducted at any stage as necessary.

SOP for Inspection of EC

Internal Inspection: The Member Secretary is responsible for organizing and maintaining EC records, including all protocols, correspondence, meeting minutes, and decisions. Regular internal reviews of compliance with SOPs and regulatory requirements are conducted.

External Inspection & Audit: The EC and institutional leadership must permit and cooperate with external audits or inspections by regulatory authorities and accreditation agencies, providing full access to all documentation.

Compliance with Guidelines: EC must ensure adherence to ICMR, CDSCO, Schedule Y, GCP, and institutional guidelines, with all findings and required corrective actions documented.

Response to Findings: Any deficiencies identified in internal or external inspections are discussed in meetings and addressed by revising processes or providing additional training as needed.

Documentation & Archiving: All inspections, communications, and corrective actions are recorded and archived securely for future reference and audit purposes, with records retained for a minimum period as per regulation.

These procedures ensure rigorous, transparent, and regulation-compliant review and inspection of EC processes, safeguarding ethical standards in all research activities.

28. Audio Visual recording of the informed consent process

The SOP for **audio-visual (AV) recording of the informed consent process** at Manubhai Patel Dental College & Hospital EC adheres to requirements under Schedule Y and ICMR guidelines for

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Vadodara, Gujarat.

certain research, especially regulatory clinical trials. The process is focused on ensuring transparency, participant protection, and proper documentation during research involving human participants.

SOP for Audio-Visual Recording of Informed Consent

Applicability

- **AV recording is mandatory** for clinical trials as per regulatory requirements or when directed by the Ethics Committee or applicable law (e.g., New Drugs & Clinical Trials Rules, 2019, Schedule Y)
- It may also be deemed necessary by the EC for vulnerable populations, high-risk studies, or whenever participant understanding and rights need added assurance.

Steps in SOP

1. Preparation

- The participant and the legally acceptable representative (if applicable) must be informed beforehand about the purpose of AV recording and their rights.
- Consent for AV recording itself must be documented in writing before the recording begins.

2. Environment

- Conduct the AV recording in a private and comfortable environment ensuring confidentiality and minimizing disturbances.
- Only essential personnel (investigator, participant, witness if required) should be present.

3. AV Recording Procedure

- Capture the entire informed consent discussion, including:
- Explanation of the study, risks, benefits, procedures, alternatives, and rights.
- Participant's questions and responses.
- Reading (or verbal explanation if illiterate) of the informed consent form.
- Confirmation from the participant regarding understanding and willingness.

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- Both the participant and (where applicable) the legally acceptable representative and impartial witness (if the participant is illiterate) must provide consent on camera.
- The date and time must be clearly recorded.

4. Data Protection and Storage

- AV recordings are confidential documents and must be stored securely in a restricted-access environment by the Principal Investigator.
- Maintain backup copies as per institutional data management policy.
- Retain recordings for the duration specified by the EC/institutional policies or relevant regulations (typically, at least 5 years post-study).

5. Access and Review

- AV recordings will be accessible for review only by authorized EC members, regulatory inspectors, and auditors, with documented access logs.
- Any access or use of the AV recordings must be approved in writing by the EC.

6. Breach or Deviation

- Any issues (technical errors, participant withdrawal of consent for recording) must be reported to the EC, with alternate measures undertaken as per EC direction.
- The EC may require a written justification for failure to complete or appropriately store the AV record.

7. Destruction

- After the retention period, AV recordings must be destroyed securely, with documentation of destruction reviewed and approved by the EC.

Documentation

- AV consent process details (reason for AV, participants involved, consent status, storage details) must be documented in the research file and reported during EC reviews or audits.
- Any waiver or exception (such as for non-feasible AV recording) must be approved by the EC before study initiation and included in the minutes.

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29. References

(1) World Health Organization, Operational Guidelines for EC that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996http://www.ich.org/LOB/media/MEDIA482.pdf

(2) CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm

(3) ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf

(4) Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) http://www.cdsco.nic.in/html/Schedule-Y%20 (Amended%20Version- 2005) %20original.htm (5) European Convention on Human rights (1997).http://conventions.coe.int/treaty/en/treaties/html/164.htm

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

1. List of Forms with Purpose & Use case details

For EC Members and Institutional Use

Form Title	Purpose	When/Who Uses	Core Sections/Content
Form Code: 01 Annexure 1: Conflict of Interest Declaration Form	Declaration of any actual/potential conflict of interest regarding a study	All EC members (for each meeting/study proposal)	EC member details, study/proposal title, nature of conflict, declaration statement, signature/date
Form Code: 02 Confidentiality Agreement	Undertaking to maintain confidentiality of all EC materials	Every EC member, guest, observer, or invited expert at induction and for each new SOP/version	Name, designation, scope of confidential material, prohibition on disclosure, disciplinary consequences, signatures
Form Code: 03 Consent Letter by EC Members	Consent to serve on the EC, acknowledging responsibilities and obligations	All newly appointed EC members before first meeting	Name, qualifications, role, acceptance statement, signature, date
Form Code: 04 Training Certificates	Documentation of research ethics/GCP training	All EC members (at induction and annually)	Certificate, training details, date, trainer/institution
Form Code: 05 Attendance Register	Record of attendance for meetings	All present at each EC meeting (members and authorized observers/guests)	Name, date, role, signature
Form Code: 06 Appointment Letter	Official appointment for each EC member	Issued by Head of Institution/Dean	Member's name, tenure, responsibilities, terms of service, renewal/termination terms

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

For Applicants/Researchers

Form Title	Purpose	When/Who Uses	Core Sections/Content
Form Code: 07 **EC Application/Submission Form**	Submission of new or revised research proposals for EC review	Principal Investigator (PI) / applicant	Project title, PI/co-investigator details, protocol summary, study design, risk assessment, participant info, budget/funding, GCP Certificate, COI disclosure
Form Code: 08 **Request for Approval to Conduct a Study (BDS/MDS/Faculty)**	Formal request to EC for reviewing and approving research (especially academic theses)	PG students (MDS/BDS), faculty investigators	Request letter, project details, expected outcomes, supervisor name, signature
Form Code: 09 **Study Protocol Submission Checklist**	Ensures submission of all required documents for EC review	PI/applicant at proposal submission	Covers all items listed in IC/SOP (protocol, consent forms, CRFs, investigator's brochure, etc.)
Form Code: 10 **Informed Consent Form (ICF) and Participant Information Sheet (PIS)**	Documenting informed consent of participants	PI/applicant as part of the study submission	Study summary, procedures, risks/benefits, voluntary participation, contact, withdrawal clause, participant/LAR/witness sign

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Form Title	Purpose	When/Who Uses	Core Sections/Content
Form Code: 11 **Conflict of Interest Disclosure Form (for Investigators)**	Declaration of any actual/potential conflict of interest by investigator(s)	PI/applicant for each new submission or amendment	Investigator details, study details, conflict description, signature/date
Form Code : 12 **Request for Exemption/Expedited Review**	To formally request special category review pathways	PI/applicant as needed	Justification, study risk assessment, protocol details
Form Code : 13 **Protocol Amendment Submission Form**	Submission of protocol amendments for EC review	PI/applicant when making study changes	Amendment summary, rationale, affected sections, updated documents
Form Code : 14 **Progress/Continuing Review Report Form**	Submission of annual/periodic status reports	PI/applicant as per scheduled reviews	Study progress summary, SAEs, protocol deviations, updated risk-benefit, compliance
Form Code : 15 **Final Report/Study Completion Form**	Submission of summary after study closure	PI/applicant after study completion	Results summary, adverse events, participant follow-up, protocol adherence statement, data confidentiality confirmation

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Form Title	Purpose	When/Who Uses	Core Sections/Content
Form Code : 16 **Serious Adverse Event (SAE) Reporting Form**	Immediate reporting of study-related SAEs	PI/applicant within regulatory timelines	Event description, relation to study, action taken, outcome, notification details
Form Code : 17 **Request for Waiver of Consent**	Application for EC permission for waiver of written/verbal consent	PI/applicant for eligible studies	Risk assessment, justification, confidentiality measures
Form Code : 18 **Appeal or Complaint Form**	To address grievances related to EC decisions or administrative issues	Investigator or affected parties	Statement of issue, supporting documents, relief sought
Form Code : 19 **Guest/Observer Request Form**	Permission to attend EC meeting as observer	Prospective members, auditors, trainees	Name, affiliation, reason, confidentiality agreement

Institutional Maintenance and Record Forms

Form Title	Purpose	Who Uses	Content
Form Code : 20 **Study File/Archive Log**	Track and archive study records	EC Secretariat	Study ID, documents received, dates, retrieval/return logs

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Form Title	Purpose	Who Uses	Content
Form Code : 21 **Monitoring Visit Report**	Document site visits	EC monitoring team	Date, findings, observations, PI responses, follow-up actions

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

2. FORM – 01 – Conflict of Interest Declaration form (Annexure 1)

CONFLICT OF INTEREST DECLARATION FORM FOR ETHICAL COMMITTEE MEMBERS (ANNEXURE 1)

I am aware of the policy of the Ethics Committee (EC) regarding Conflict of Interest (COI) and that no reviewer may participate in the review, comment, or decision-making of any activity in which he/she has an actual or potential COI, except to provide information as requested by the EC.

I declare

.....

(actual or potential COI)

in relation to the proposal entitled

"..... .."

submitted for review.

The reason for COI is

.....

.....

.....

I will refrain from the review, processing, discussion, and decision-making regarding this study.

Signature of EC Member: ..... **Date:** .....

Chairperson's Signature: ..... **Date:** .....

Instructions:

- Complete and sign this form **before** the review/discussion of the indicated proposal.
- The declaration and any recusal must be recorded in the official EC meeting minutes and archived for audit purposes.[2][1]
- For queries regarding this policy, contact the Member Secretary.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

3. FORM – 02 – Confidentiality Agreement

CONFIDENTIALITY AGREEMENT -

FOR INSTITUTIONAL ETHICS COMMITTEE MEMBERS, ALTERNATE MEMBERS, AND INVITED EXPERTS

1. Member Details

Name:	
Profession:	
Affiliation:	
Designation/Role:	
Address:	

2. Agreement Preamble

I, the undersigned, having been appointed as a member/alternate member/invited expert of the Institutional Ethics Committee (IEC/EC) of Manubhai Patel Dental College & Hospital, hereby acknowledge and agree to abide by the confidentiality requirements and obligations as stipulated by the Committee's Standard Operating Procedures and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

3. Scope of Confidentiality

- I understand that all information, documents, protocols, participant data, meeting minutes, discussions, and proceedings ("Confidential Information") obtained during IEC/EC business are to be treated as strictly confidential and will not be disclosed, discussed, or disseminated to any unauthorized person or third party under any circumstances except as required by law or with official IEC/EC authorization.SOP-for-IEC-MPDC.docx
- This applies to hard copy, electronic, and verbal communications, as well as to any notes or copies made during the discharge of my role.

4. Obligations

- I will not make unauthorized copies, retain personal notes of confidential documents, or otherwise use Confidential Information for any purpose other than for IEC/EC business.

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- I understand that breach of confidentiality may warrant termination of my IEC/EC membership and/or disciplinary action as per institutional policy.4-Terms-of-Reference-Query-Replied-August-2025.docx+1

5. Condition for Recusal/Disclosure

- If, at any time, I believe I am unable to comply with confidentiality obligations, I will immediately inform the IEC/EC Chairperson/Member Secretary and recuse myself from related proceedings.SOP-for-IEC-MPDC.docx
- I acknowledge that independent consultants and guests/observers are also bound by this agreement before participation in IEC/EC proceedings.

6. Declaration and Signature

I hereby confirm I have read, understood, and agree to adhere to the confidentiality policies and procedures of the IEC/EC.

Signature:	
Name:	
Date:	

For Office Use Only:

Date received: _____

Signed by: (Chairperson/Member Secretary) _____

Date: _____

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

4. FORM – Consent Letter by EC Members

CONSENT LETTER BY EC MEMBERS

To
The Chairperson,
Institutional Ethics Committee (EC),
Manubhai Patel Dental College & Hospital,
Vadodara

Subject: Consent and Undertaking for Membership in the Institutional Ethics Committee

I, Dr./Mr./Ms. _____, hereby confirm my willingness to serve as a member of the Institutional Ethics Committee (IEC/EC) of Manubhai Patel Dental College & Hospital for the prescribed tenure. In accepting this role, I agree to the following:

1. **I have received, read, understood, and undertake to abide by the Terms of Reference (ToR), Standard Operating Procedures (SOPs), and policies of the EC as provided to me.**
2. **I agree to perform the responsibilities expected of EC members, including regular and active participation in meetings, review of research proposals, and making independent, informed, and unbiased decisions in the best interests of research participants and ethical standards.**
3. **I will maintain complete confidentiality regarding all matters (scientific documents, investigator and participant information, EC decisions, discussions, proprietary data) reviewed during my tenure as an EC member.**
4. **I will declare any actual, potential, or perceived conflicts of interest in line with the EC's policy and recuse myself from discussions and decisions where such conflicts exist.**
5. **I agree to undergo all required initial and continuing training in research ethics, Good Clinical Practice (GCP), and any other topic as mandated by the EC.**
6. **I commit to comply with national (ICMR, NDCT Rules, CDSCO) and international ethical guidelines in the discharge of my EC responsibilities.**
7. **I consent to my name, profession, and EC affiliation being placed in the public domain as required for transparency.**

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

8. **I accept that my continued membership is subject to compliance with the requirements of the EC, including maintaining adequate attendance and upholding the highest ethical standards.**

9. **I understand that breach of confidentiality, non-participation, or violation of institutional or ethical norms may result in termination of my appointment.**

Date:_____
Place: _____

Signature: _____
Name (in block letters): _____
Designation: _____
Contact Address & Phone/Email: _____

For Office Use Only:
Accepted and inducted into the EC on (Date): _____

Chairperson, EC: _____ **Member Secretary, EC:** _____

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

5. FORM – 04 – Training certificates Submission Form

TRAINING CERTIFICATES SUBMISSION FORM

Section	Details
EC Member Name	
Designation/Role	
Affiliation	
Date of Appointment	

Initial/Continuing Education/Refresher (Annual/Other)

(Repeat for each refresher session as applicable)

Year	Course Title/Workshop	Provider/Organizer	Date	Certificate Attached (Y/N)

D. Member Declaration

I confirm that the above record of my research ethics training is complete and true.
I undertake to update my training as required and submit new certificates to the IEC office.

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Signature of EC Member:	
Date:	

Instructions:

- Attach photocopies or scans of all certificates listed above.
- Submit completed form to the IEC Secretariat upon appointment and after each training or continuing education event.
- Secretariat will check, verify, and archive under the member's file.SOP-for-IEC-MPDC.docx+1

For IEC Secretariat Office Use

- Date received:
- Verified by:
- Archives (File/Folder No.):
- Next training due by (date):

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

6. FORM – 05 – Attendance Register

ATTENDANCE REGISTER

Meeting Date	Meeting Type (Regular/Emergency)	Meeting Venue	Start Time	End Time

Sr. No.	Name of EC Member	Designation (Chairperson / Member Secretary / Member / Invited Expert / Observer)	Signature	Time In	Time Out	COI Declared (Yes/No/NA)	Remarks (e.g., Absence Reason, Recusal)

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Sr. No.	Name of EC Member	Designation (Chairperson / Member Secretary / Member / Invited Expert / Observer)	Signature	Time In	Time Out	COI Declared (Yes/No/NA)	Remarks (e.g., Absence Reason, Recusal)

Instructions:

- Each member (including invited experts and observers) must sign in and out.
- *COI Declared*: Indicate if a Conflict of Interest was declared during this meeting for any agenda item; provide details in Remarks.
- *Remarks*: Note absences, late arrivals, or recusal due to COI as per SOP.
- The Member Secretary will aggregate and review the register for documentation and regulatory compliance.

Certification:

I hereby certify that the above is a true and accurate record of attendance for the IEC/EC meeting on the stated date.

Member Secretary Name/Signature	Date

This form should be printed and securely archived with all official IEC/EC meeting documents.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

7. FORM – 06 – Appointment Letter

APPOINTMENT LETTER

Letter Ref. No.: _____ **Date:** _____

From:
Dean/Principal,
Manubhai Patel Dental College & Hospital
Vishwajyoti Ashram, Munjmahuda,
Vadodara – 390011, Gujarat

To,

_____

_____

Subject: Appointment to the Institutional Ethics Committee (EC)

Dear Sir/Madam,

I am pleased to inform you that, following the recommendations and selection process of the Manubhai Patel Dental College, you have been appointed to serve as the _____ *of the Institutional Ethics Committee (EC)* of Manubhai Patel Dental College.

Your key responsibilities will include:

- Attending IEC/EC meetings regularly and actively participating in ethical reviews and deliberations.
- Reviewing research proposals in an objective, unbiased, and independent manner.
- Maintaining confidentiality of all committee discussions, documents, and decisions.
- Declaring any conflict of interest as per IEC/EC policy prior to discussions.
- Complying with all SOPs, institutional policies, and ICMR National Ethical Guidelines.
- Signing and adhering to **Confidentiality and Conflict of Interest Agreements**.

Terms of Appointment:

1. **Role:**
2. **Tenure:** [

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

3. **Honorarium:** As per decision of the Dean/Principal.
4. **Training:** Mandatory initial and periodic training in research ethics and Good Clinical Practice (GCP).
5. **Termination:** Appointment may be terminated for reasons including repeated absenteeism, non-performance, breach of confidentiality, or violation of institutional/ethical policies.

Kindly confirm your acceptance by signing and returning the attached consent form (Form-3) within **10 days** of receipt.

We look forward to your valuable contribution towards upholding high ethical standards in research.

Yours sincerely,

Dean
Manubhai Patel Dental College & Hospital

Enclosures:

1. Consent Form (Form-3)
2. Conflict of Interest Declaration Form
3. Confidentiality Agreement
4. SOPs and IEC/EC Guidelines

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

8. FORM – 07 – EC Application/Submission Form

INSTITUTIONAL ETHICS COMMITTEE APPLICATION/SUBMISSION FORM

1. General Information

- **Title of the Study/Project:**
- **Department:**
- **Principal Investigator (PI):**
  - Name:
  - Designation:
  - Affiliation (internal/external):
  - Contact Address:
  - Email:
  - Phone:
- **Co-Investigators (if any):**
  - Name(s) and Affiliation(s):
- **Collaborating Institutions (if any):**
- **Type of Proposal:**
  - Student (BDS/MDS/Thesis)
  - Investigator-Initiated (Institutional)
  - Sponsored Clinical Trial
  - Externally Sponsored Project
  - Other: _____
- **Funding Source (If applicable):**
- **Clinical Trial Registration Number (if applicable):**

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

2. Background and Rationale

- **Lay Summary (in simple language):**
- **Scientific Background and Rationale:**
- **Objectives/Aims of the Study:**

3. Study Design Details

- **Study Design/Methodology:**
- **Sample Size (with justification):**
- **Duration of Study:**
- **Study Site(s):**
- **Inclusion/Exclusion Criteria:**
- **Description of Procedures/Interventions:**

4. Participant Information

- **Population and Sampling:**
- **Vulnerable Groups involved (if any):**
  - Yes / No (Specify details and safeguards if Yes)
- **Informed Consent:**
  - Attach copy of Patient Information Sheet and Informed Consent Form in English and vernacular

5. Risk-Benefit Assessment

- **Potential Risks (physical, psychological, social, legal, etc.):**
- **Measures for Risk Minimization:**
- **Potential Benefits (to participants/society):**

6. Data Management

- **Confidentiality and Privacy Measures:**

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- **Data Storage and Retention Plan:**
- **Plans for Publication/Dissemination:**

7. Compensation and Medical Management

- **Provision for Compensation in case of research-related injury:**
- **Medical Management Arrangements:**
- **Insurance (attach policy if applicable):**

8. Ethical, Legal, and Regulatory Compliance

- **Approval from other ECs (if multicentric):**
- **DCGI/CDSCO approval (for regulatory trials):**
- **Other administrative/regulatory approvals (if any):**
- **Conflict of Interest Declaration (by all investigators):**
- **Good Clinical Practice (GCP) Training Certificates:**

9. Attachments (tick and attach as applicable)

- Study Protocol (with all amendments)
- Informed Consent Documents (English & local language)
- Patient Information Sheet
- Case Record Forms/Questionnaires/Tools
- Funding Documents / Letter
- Curriculum Vitae (PI, Co-Investigators)
- Institutional permissions (if required)
- Undertaking Signed by PI
- Insurance Policy / Indemnity
- DCGI/Regulatory approvals
- Previous EC approvals (if multicentric)

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- Confidentiality/COI signed agreements
- Training Certificates for Human Protection/GCP
- List of ongoing studies by PI

10. Declaration by the Investigator

I/We hereby declare:

1. I/We have read and understood the latest version of the Institutional Ethics Committee SOPs and ICMR Ethical Guidelines.
2. I/We agree to comply with all ethical, regulatory, and data confidentiality requirements.
3. I/We will report to the EC all amendments, SAEs, deviations, and submit periodic/final reports.
4. I/We have not submitted this proposal to another EC for concurrent review (unless multicentric).
5. I/We declare that all information provided is accurate and complete to the best of my/our knowledge.

Principal Investigator:
Signature: _____
Date: _____

Co-Investigators:
(Signatures & Dates)

Office Use Only

- **EC Submission No:**
- **Date of Receipt:**
- **Type of Review (Full/Expedited/Exempt):**
- **Remarks (Initial Screening):**

9. FORM – 08 – Request for Approval to Conduct a Study

REQUEST FOR APPROVAL TO CONDUCT A STUDY

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

(For: BDS/MDS Students and Faculty)

To:

The Chairperson,
Institutional Ethics Committee (IEC),
Manubhai Patel Dental College & Hospital, Vadodara

Subject: Request for Ethical Approval to Conduct a Research Study

1. Investigator Details

- **Name of Principal Investigator (Student/Faculty):**
- **If Student – Course/Year:**
  - BDS / MDS / Faculty
  - **Department:**
- **Institution:**
- **Contact Information:**
  - Address:
  - Phone/Mobile:
  - Email:

2. Supervisory Personnel

- **Guide/Supervisor Name:**
  - Department:
  - Designation:
- **Co-guide(s), if any:**

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- Name(s) and Affiliation(s):

3. Study/Project Details

- **Full Title of Study/Thesis/Dissertation/Project:**
- **Short Title (if any):**
- **Study Centre(s):**
- **Proposed Study Period:**
  - (From mm/yyyy – To mm/yyyy)

4. Study Information

- **Type of Study:**
  - Academic / Thesis / Faculty Research / Investigator-Initiated / Sponsored
- **Study Design:**
  - Prospective / Retrospective / Randomized / Observational / Case-Control / Others (specify)
- **Objectives (Primary and Secondary):**
  - Primary:
  - Secondary:

5. Ethics and Safety

- **Summary of Protocol and Methodology:**
- **Inclusion and Exclusion Criteria:**
- **Sample Size (with justification):**
- **Risks and Benefits to Participants:**

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- **Details of Procedures/Interventions:**
- **Privacy and Confidentiality Measures:**
- **Plan for obtaining Informed Consent:**
    - Languages (English/Hindi/Other):
    - *Attach draft Participant Information Sheet & Informed Consent Form*
- **Compensation and Care (if applicable):**
- **Is this study funded?** Yes / No
    - If Yes, funding source:

---

6. Regulations and Declarations

- **Has this study been approved by any other Ethics Committee?** Yes / No
    - If Yes, details:
- **Clinical Trial Registration Number (if applicable):**
- **Declaration of Conflicts of Interest:**
- **Relevant regulatory approvals (if applicable):**

---

7. Checklist of Attachments

- Study Synopsis/Protocol (structured abstract)
- Detailed Methodology
- Participant Information Sheet & Consent Form (English & local language)
- CV of PI and Co-investigators/Guides
- Author Contribution Form (Annexure 5, if applicable)
- Data Collection Format / Case Record Form (CRF)

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- Other supporting documents (statistical analysis plan, sponsorship letter, permission letters, etc.)

8. Investigator's Undertaking

I, the undersigned, certify that:

- The information provided is accurate and complete to the best of my knowledge.
- I will conduct the study as per the approved protocol and EC guidelines.
- Participants' rights, safety, dignity, and confidentiality will be protected throughout the research.
- No study procedure will be initiated without IEC approval.

Signature of Principal Investigator
Name:
Date:

Signature of Guide/Supervisor
Name:
Date:

Signature of Head of Department
Name:
Date:

For Office Use:

- Date of receipt:
- EC Application number:
- Documents checked by:
- Comments/remarks (if any):

10. FORM – 09 – Study Protocol Submission Checklist

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

STUDY PROTOCOL SUBMISSION CHECKLIST

Protocol Submission Checklist

This checklist must be completed and submitted with every new protocol application, amendment, or resubmission to the IEC. The investigator is responsible for ensuring all items are provided, as per ICMR National Ethical Guidelines.

S. No.	Document/Requirement	Attached	Not Applicable	Comments / Version No.
1	Cover letter addressed to the Member Secretary	☐	☐	
2	Completed Protocol Submission Application Form	☐	☐	
3	Protocol/Project Proposal (signed by all investigators)	☐	☐	
4	Summary/Abstract/ Lay Summary	☐	☐	
5	Rationale/Background of the Research	☐	☐	
6	Objectives and Endpoints	☐	☐	
7	Details of Research Team (CVs, roles, training/GCP certificates)	☐	☐	

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S. No.	Document/Requirement	Attached	Not Applicable	Comments / Version No.
8	Informed Consent Documents (English & local language), with translation certs	☐	☐	Version: _____
9	Patient/Participant Information Sheet (PIS)	☐	☐	
10	Case Record Forms/Questionnaire/Diaries	☐	☐	
11	Recruitment methods and advertisements	☐	☐	
12	Investigator's Brochure/Device Literature/Drug Data Sheet	☐	☐	
13	Details of Funding Source & Budget Allocation	☐	☐	
14	Regulatory Approvals (CDSCO/other, if applicable)	☐	☐	
15	Administrative Approvals (Institution/HOD)	☐	☐	
16	Insurance/Indemnity Policy (wherever applicable)	☐	☐	
17	GCP/Research Ethics Training Certificates (preferably within last 5 years)	☐	☐	
18	COI (Conflict of Interest) Declaration Forms (all Investigators/EC members)	☐	☐	

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Vadodara, Gujarat.

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S. No.	Document/Requirement	Attached	Not Applicable	Comments / Version No.
19	Confidentiality Agreement (all Investigators/Collaborators/EC members)	☐	☐	
20	List of ongoing studies by the Principal Investigator(s)	☐	☐	
21	Data Storage & Confidentiality Protection Plan	☐	☐	
22	Plan for Handling Adverse Events/Serious Adverse Events (AE/SAE)	☐	☐	
23	Safety monitoring plan/DSMB (if applicable)	☐	☐	
24	Provisions for compensation to participants (for research-related harm)	☐	☐	
25	Material Transfer Agreement (for collaborative/multicentre research)	☐	☐	
26	Any MoU or Inter-institutional agreements	☐	☐	
27	Electronic consent process documentation (if applicable)	☐	☐	
28	Protocol amendments history (for resubmissions)	☐	☐	

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Vadodara, Gujarat.

INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

S. No.	Document/Requirement	Attached	Not Applicable	Comments / Version No.
29	Progress/final/completion reports (for continuing review/closeout)	☐	☐	
30	Other relevant supporting documents (specify): _____	☐	☐	

Declaration (to be signed by Principal Investigator)

I confirm that all the above relevant documents have been included and that this submission complies with IEC and ICMR requirements. Incomplete submissions may be returned without review.

- Name and signature of Principal Investigator:
- Date:

Instructions:

- Tick 'Attached' for items enclosed; 'Not Applicable' if not relevant to this study.
- Provide version numbers/dates for all key documents.
- Retain a copy of this checklist for reference.
- Attach this checklist as the cover sheet of your protocol submission package.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

11. FORM – 10 – Informed Consent & Participant Information Sheet

INFORMED CONSENT FORM (ICF) AND PARTICIPANT INFORMATION SHEET (PIS)

Participant Information Sheet (PIS)

Study Title:
Protocol Number (if applicable):
Principal Investigator:
Institution:
Contact Details (PI/EC):

Introduction

- This is an invitation to consider participating in the research study titled above. The purpose of this information sheet is to help decide whether to take part.
- Please read this information carefully. Ask the investigator any questions you may have for clarification before you decide.

Purpose of the Research

- Explanation of the study objectives in simple language, including why the research is being conducted and the expected outcomes.

Study Procedures

- Description of what participation involves: visits, procedures, duration, follow-up, and expected time commitment.
- Number of participants in the study.

Potential Benefits

- Explanation of any expected direct or indirect benefits to participants, the community, or others.

Potential Risks and Discomforts

- Details of any reasonably foreseeable risks, discomforts, or inconveniences arising from participation.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Confidentiality

- The information provided will be kept confidential to the extent permitted by law.
- Explanation about access and storage of data, coding/anonymization processes.
- Potential limitations to absolute confidentiality.

Compensation/Medical Care for Injury

- Details regarding free treatment and/or compensation for research-related harm as approved by EC.

Voluntary Participation and Withdrawal

- Participation is entirely voluntary.
- Right to refuse or withdraw from the study at any time without having to give a reason and without affecting rights or usual care.

Payment/Reimbursements

- Information on compensation/reimbursement for time, travel, and any other incidental expenses, if applicable.

Alternative Procedures

- Alternatives to participation, if relevant.

Contact Information

- For study-related queries: Name, phone/email of PI.
- For complaints about rights as a research participant: Contact details for EC Chairperson/Member Secretary.

Declaration

- The study has been reviewed and approved by the Institutional Ethics Committee.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Informed Consent Form (ICF)

Participant Name:
Participant Address:
Participant ID/No:
Name of Legally Acceptable Representative (if applicable):
Name of Impartial Witness (if applicable):

Consent Statement

- I have read/been read and understood the information sheet for the above study.
- I have had the opportunity to ask questions regarding the study and my participation.
- I voluntarily agree to participate in this study.
- I understand that I may withdraw from the study at any time without disadvantage.
- I agree to the audio/AV recording of the informed consent process (if applicable).
- I understand that necessary data may be accessed by regulatory authorities, EC members, or auditors for monitoring and review.
- I have received a copy of this consent form and the information sheet.

Signatures

- Participant: _____ Date: _____
- (Or) Thumb impression if illiterate
- Legally Acceptable Representative (if applicable):
  Name: _____ Signature: _____ Date: _____
- Impartial Witness (if participant/LAR is illiterate):
  Name: _____ Signature: _____ Date: _____
- Person obtaining consent (Investigator/Delegate):
  Name: _____ Signature: _____ Date: _____

EC Approval Stamp:
(Signature/Seal of EC Chairperson or Member Secretary)

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

12. FORM – 11 – Conflict of Interest Disclosure (Investigators)

CONFLICT OF INTEREST DISCLOSURE FORM (FOR INVESTIGATORS)

A. Investigator Details

- **Name:** _____
- **Department/Unit:** _____
- **Designation/Role in Study:** _____
- **Study Title:** _____
- **Protocol Number (if any):** _____
- **Date of Submission:** _____

B. Disclosure of Conflict of Interest

1. **Do you, your immediate family members, or associates have any financial or non-financial interests, commitments, or relationships with any entity related to the proposed research?** (Examples: Sponsorship/funding, consultancy, employment, honoraria, equity interest, intellectual property rights, personal relationships, academic competition, or political interests.)
    - No, there is no actual, potential, or perceived conflict of interest.
    - Yes, details are provided below.
2. **If YES, please specify (tick all that apply and provide details):**
    - Financial interest (e.g., sponsorship, grants, honoraria, stocks, intellectual property rights)
    - Professional involvement or consultancy
    - Personal relationship (e.g., with sponsor/PI/co-investigator)
    - Academic interest/competition
    - Other (please specify): _____

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Brief Description of Conflict(s):

3. **Describe any steps taken or planned to manage, minimize, or eliminate this (these) conflict(s):**
   (e.g., recusal from certain study roles, disclosure to participants/EC, independent data analysis, etc.)

C. Investigator's Statement

I hereby declare that the information provided above is accurate to the best of my knowledge. I undertake to promptly inform the Ethics Committee if any new conflicts arise or if circumstances regarding the disclosed conflicts change during the course of the study.

- **Signature of Investigator:** _____
- **Date:** _____

D. To be completed by the EC Secretariat

- **Received by (Name, Designation):** _____
- **Date:** _____
- **Review/Decision/Management Plan:**

- **Signature (Member Secretary/Designated EC Member):** _____

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

- **Date:** _____

Instructions:

- Attach additional pages if more space is required.
- Submit this form with the main research proposal and prior to EC review.
- This form is required for all investigators, co-investigators, and key research personnel.

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

13. FORM – 12 – Request for Exemption/Expedited Review

REQUEST FOR EXEMPTION/EXPEDITED REVIEW

To be completed by the Principal Investigator and submitted to the IEC Secretariat. Review category will be determined by the IEC.

Section 1: Investigator and Project Details

Item	Information to be Provided
1. Project Title	
2. Principal Investigator (Name, Designation, Department)	
3. Co-Investigators (Name & Department)	
4. Contact Information (Phone & Email)	
5. Category (Tick One)	☐ Student Project ☐ Faculty/Investigator Project ☐ Sponsored/External Study
6. Funding/Support (Yes/No, Details)	
7. Has the protocol been approved by Scientific/Synopsis/Other Committee? (Attach proof)	

Section 2: Request Type (Tick Appropriate Option)

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Type Requested	Check
Exemption from IEC Review	☐
Expedited IEC Review	☐

Section 3: Justification (Mandatory)

Attach additional sheets if needed.

- Justification for exemption/expedited review (explain basis as per ICMR/IEC SOP criteria):
  - [Briefly describe the research, risks involved, type of data/samples, interventions, etc.]
  - [Explain why exemption or expedited review is appropriate (minimal/no risk, non-identifiable data, public datasets, minor amendment, urgent public health, etc.)]
  - [Specify if the research involves vulnerable populations, and address relevant safeguards.]

Section 4: Study Details

- Study Design (e.g., survey, chart review, observational, interventional, minimal risk):
- Population/Participants Involved (including any vulnerable group):
- Data/Samples to be Used (e.g., anonymized, identifiable, left-over, public sources):
- Will there be direct contact with participants? (Yes/No):
- Will identifiable information be collected? (Yes/No):
- Plans for consent/waiver of consent (if relevant; provide justification):

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INSTITUTIONAL ETHICS COMMITTEE (EC) FOR RESEARCH

Section 5: Attachments Checklist

Document	Enclosed (✓)
1. Detailed Study Protocol	
2. Filled Application Form (IEC/MPDC Standard)	
3. Justification Letter for Exemption/Expedited Review	
4. Participant Information Sheet and Consent Form (if applicable)	
5. Data Collection Tools/Questionnaires	
6. Ethics Committee Approvals (if previously submitted elsewhere)	
7. Any Additional Supporting Documents	

Section 6: Declaration

I/we declare that the above information is true and correct. I/we understand that the IEC will assign the appropriate review category in accordance with the SOP and ICMR guidelines. Any changes to the protocol will be promptly reported.

Name & Signature of Principal Investigator	Date

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- IEC Serial No.:
- Date Received:
- Review Category Assigned: ☐ Exemption ☐ Expedited ☐ Full
- Remarks:
- Reviewed by:
- Date of IEC Meeting/Decision:

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14. FORM – 13 – Protocol Amendment Submission Form.

PROTOCOL AMENDMENT SUBMISSION FORM

Section 1: Protocol Information

- **Title of Original Protocol / Study**:
  [Enter full title as per initial submission]
- **IEC Reference Number**:
  [Enter IEC approval/reference no.]
- **Principal Investigator (PI)**:
  Name:
  Department:
  Designation:
  Contact Information:
- **Date of Original IEC Approval**:
  [DD/MM/YYYY]
- **Sponsor / Funding Agency (if any)**:
  [Enter details]

Section 2: Amendment Details

- **Type of Amendment** (tick all that apply):
  □ Change in protocol procedures
  □ Change in inclusion/exclusion criteria
  □ Change in study sites
  □ Change in informed consent process/documents
  □ Change in investigators or study staff
  □ Change in study design/methodology
  □ Others (please specify): _____
- **Reason / Rationale for Amendment**:
  [Briefly describe the reason for submitting the amendment, scientific/ethical justification, and impact on participant safety or study validity]

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- **Summary of Changes**:
  [Tabulate or bullet-point all sections/documents changed. Attach copy of marked-up/revised documents.]

Section 3: Impact Assessment

- **Does this amendment affect the risk/benefit ratio for study participants?**
  □ Yes □ No (If yes, explain)
- **Does this amendment impact ongoing participants?**
  □ Yes □ No
  [If yes, describe required re-consent or additional follow-up.]
- **Is re-consent from currently enrolled participants required?**
  □ Yes □ No
  [If yes, submit revised consent documents.]
- **Is any regulatory approval required?**
  □ Yes □ No
  [If yes, attach copies.]

Section 4: Documentation Checklist

Attach the following documents (select as applicable):

- □ Cover letter explaining the amendment
- □ Revised protocol (with changes highlighted)
- □ Clean and tracked versions of amended documents
- □ Revised consent documents
- □ Updated investigator/team CVs (if applicable)
- □ Regulatory approvals (if applicable)
- □ Other supporting documents (specify): _____

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Section 5: Declaration by Principal Investigator

I hereby declare that the amendment submitted is accurate and complete. I affirm that necessary changes will be implemented only after approval from the IEC.

PI name & signature: _____
Date: _____

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- **Date Received:** _____
- **Registration No.:** _____
- **Type of Review**: □ Expedited □ Full Board
- **Date of EC Review:** _____
- **Final EC Decision:** □ Approved □ Modifications Required □ Rejected
- **Comments/Conditions:** _____
- **Signatures (Chairperson/Member Secretary):** _____
- **Date:** _____

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15. FORM – 14 – Progress/Continuing Review Report Form

PROGRESS/CONTINUING REVIEW REPORT FORM

1. Study Details

- **Title of Study:**
- **Principal Investigator (PI):**
- **Department:**
- **Study Reference Number/EC Approval Number:**
- **Date of Initial EC Approval:**
- **Review Period Covered by This Report (From – To):**
- **Date of Submission of This Report:**

---

2. Study Status (Tick as applicable)

- Ongoing, no changes
- Ongoing with amendments (attach copy of EC approval for amendments)
- Completed (attach final report/summary)
- Suspended/Terminated (give reason and attach relevant documents)

---

3. Participant Information

- **Total number approved for enrolment:**
- **Number of participants enrolled since last review:**
- **Cumulative number enrolled in the study so far:**
- **Number completed study:**
- **Number who withdrew (with reasons):**

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- **Number lost to follow-up:**

4. Protocol Compliance

- Study conducted as per approved protocol
- Deviations/violations have occurred (If yes, provide details, reasons, and corrective measures)

5. Summary of Progress

- **Objectives/Endpoints Achieved So Far:**
- **Summary of Activities Conducted Since Last Review:**
- **Any difficulties encountered and corrective actions undertaken:**

6. Safety/Adverse Events (AE/SAE)

- **Number of Adverse Events Reported:**
- **Number of Serious Adverse Events (SAEs):**
- **SAE Details (attach separate list if applicable):**
- **Action taken:**
- **Was the EC notified of these events?** [Yes/No] (Attach acknowledgement)

7. Amendments (if any)

- **List of amendments since last review:**
- **Date of EC approval for amendments:**

8. Updated Documents Submitted

Attach as applicable:

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- Updated Protocol Version
- Updated Informed Consent Documents
- Updated Investigator Brochure/Leaflets
- Any new questionnaires or tools
- Other (specify): _____

9. Funding/Insurance

- **Any changes in funding status?** [Yes/No]
- **Insurance/Compensation arrangements status:**
  - No change
  - Change (provide details)

10. Confidentiality and Data Management

- **Have there been any breaches of privacy/confidentiality?** [Yes/No]
  If yes, describe with corrective actions.

11. Problems/Complaints

- **List any participant complaints received since the last review:**
- **Action taken to address them:**

12. Additional Information/Comments (if any)

(Any additional information, challenges faced, or suggestions to the EC.)

13. Declaration by Principal Investigator

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I hereby declare that the above information is true and complete to the best of my knowledge and that the study is being conducted in compliance with the protocol approved by the IEC.

Signature of Principal Investigator:
Date:
Contact Number & Email:

---

14. Department/Head Review (if required)

Comments of Head of Department:
Signature & Date:

---

15. For Office Use (EC Secretariat only)

- **Date received:**
- **Checked by:**
- **Remarks if any:**
- **Next Review due on:**

Instructions for Submission:

- Submit this form with all supporting documents to IEC Secretariat before the due date for continuing review.
- Incomplete forms may result in delay or suspension of study approval.

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16. FORM – 15 – Final Report/Study Completion Form

FINAL REPORT / STUDY COMPLETION FORM

Section 1: Study Identification

- **Title of Study**:
- **IEC Reference Number / Approval Date**:
- **Principal Investigator**:
    - Name:
    - Department:
    - Contact Details (Phone/Email):
- **Co-Investigator(s)** (if any):

Section 2: Key Study Details

- **Study Site(s)**:
- **Type of Study**: (e.g., Interventional/Observational/Device/Thesis/Other)
- **Date of IEC Approval**:
- **Study Start Date**:
- **Study Completion Date** (Including last patient/participant, if applicable):

Section 3: Progress & Conduct

- **Total Number of Participants Approved**:
- **Total Number of Participants Enrolled**:
- **Number of Participants Completed Study**:
- **Number of Participants Withdrawn / Lost to Follow-up**:
    - Please provide reasons for withdrawal/loss:

Section 4: Protocol Adherence & Deviations

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- **Were there any changes/deviations from the approved protocol?**
    - ☐ No
    - ☐ Yes *(If yes, provide details and IEC approval reference for amendments. Attach explanations where needed.)*

Section 5: Safety and Adverse Events

- **Serious Adverse Events/Adverse Events reported?**
    - ☐ No
    - ☐ Yes *(If yes, briefly describe type, date, actions taken, and outcomes. Attach details and IEC correspondence.)*

Section 6: Results and Outcome

- **Summary of Study Results** *(Attach full summary/report separately):*
- **Main conclusions, findings, and significance:**
- **Were study objectives achieved?**
    - ☐ Yes
    - ☐ No
    - *(Brief explanation if not achieved):*

Section 7: Confidentiality & Data Handling

- **How was confidentiality of participant data ensured?**
- **Where and how will study records/data be archived?**
    - *(Minimum five years retention as per SOP)*

Section 8: Publications/Presentations

- **Have results been published/presented?**
    - ☐ No
    - ☐ Yes *(Provide details and attach references/copies where available.)*

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- **Have all contributors been appropriately acknowledged?**
  - ☐ Yes
  - ☐ No

Section 9: Final Participant Status and Follow-up

- **Confirm follow-up of all participants per protocol:**
  - *(Attach list if needed, confirm completion or status for all participants)*
- **Benefits to participants/community, if any:**

Section 10: Principal Investigator's Declaration

I certify that this study was conducted in accordance with the IEC-approved protocol, all modifications received prior IEC approval, all adverse events were reported as required, confidentiality was maintained, and all participants' rights, safety and well-being were safeguarded.

- **Principal Investigator Name**:
- **Signature**:
- **Date**:

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- **Form and Report received on**:
- **Reviewed by**:
- **IEC Review Meeting Date**:
- **Decision**:
  - ☐ Final report accepted. Study formally closed.
  - ☐ Additional information required (specify):
  - ☐ Concerns/Action Points:
- **Signature (Member Secretary/Chairperson)**:

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- **Date:**

Attachments Checklist

- ☐ Detailed Final Study Report
- ☐ Adverse Event/SAE documentation
- ☐ Publications/Presentations (if any)
- ☐ List of participants (de-identified)

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17. FORM – 16 – Serious Adverse Event (SAE) Reporting Form

SERIOUS ADVERSE EVENT (SAE) REPORTING FORM

Field/Section	Details (to be filled by Investigator/Responsible Personnel)
1. Study Protocol Title & EC Ref. No.	
2. Principal Investigator (PI) Name	
3. Contact Details of PI	Phone: _____
4. Sponsor (if applicable)	
5. Study Site	
6. Date of EC Approval	
7. SAE Reporting Sequence Number	(if applicable; for ongoing studies)

A. DETAILS OF SERIOUS ADVERSE EVENT (SAE)

1. Date/Time SAE Occurred: _____
2. Date/Time SAE Notified to PI: _____
3. Date/Time SAE Reported to IEC/Sponsor/Regulators: _____
4. Type of SAE (tick all that apply):
   - ☐ Death
   - ☐ Life-threatening

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- ☐ Hospitalization/Prolonged hospitalization
- ☐ Significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Other (specify): _____

5. Description of SAE (clinical signs, symptoms, diagnosis, relevant history):

B. STUDY PARTICIPANT DETAILS

Field	Details
Participant Study ID	
Age/Sex	
Weight/Height	
Relevant medical history	
Concomitant medications	

C. SAE NARRATIVE & COURSE

- Brief account of the SAE (use additional sheets if necessary):
- Management/intervention provided:
- Current status/Outcome (Recovered/Recovering/Not recovered/Deceased):

D. ASSESSMENT BY INVESTIGATOR

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1. **Causality Assessment**
    - Was the SAE related to the study intervention? [ ] Yes [ ] No [ ] Possibly
    - Reason for assessment:
2. **Expectedness**
    - Was the SAE expected as per protocol/ICF/Investigator Brochure? [ ] Yes [ ] No
3. **Action taken regarding:**
    - Study intervention (continued/paused/stopped): _____
    - Participant (continued/withdrawn): _____
4. **Has this SAE led to Protocol Amendment?** [ ] Yes [ ] No
    - If yes, details:

E. REGULATORY AND IEC COMMUNICATION

- Date and mode of initial SAE reporting to IEC: _____
- Date & copy of SAE forwarded to sponsor/regulatory authority (if applicable): _____
- Any additional safety reports submitted/attached: [ ] Yes [ ] No

---

F. SIGNATURE & DECLARATION

I hereby declare the information provided is accurate and complete to the best of my knowledge.

Name	Designation	Signature	Date
Principal Investigator			

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Field	Details/Finding
Date SAE report received by IEC	
Completeness of Documentation	[ ] Yes [ ] No
Reviewers assigned (Name/Role)	
Is causality assessment adequate?	[ ] Yes [ ] No
EC Recommendations/Action taken	
Compensation required?	[ ] Yes [ ] No (If Yes, details)
Date of IEC decision/communication	
Final outcome (Closed/Follow-up needed)	
IEC Chairperson Signature	
IEC Member Secretary Signature	

Instructions:

- Submit within 24 hours of becoming aware of an SAE.
- Attach supporting documents (hospital reports, investigation findings, consent form copy, etc.).
- For fatal events, immediate notification (within 24 hours) is mandatory.
- Keep a copy in study master file and provide all details as per IEC and regulatory requirements.

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18. FORM – 17 – Request for Waiver of Consent Form

REQUEST FOR WAIVER OF CONSENT FORM

Section A: Basic Information

- **Proposal Title:**
- **Principal Investigator (PI):**
- **Department:**
- **Co-Investigators/Collaborators (if any):**
- **Date of Submission:**
- **IEC Reference Number (if already assigned):**

Section B: Study Details

1. **Type of Study/Project:**
   (e.g., Retrospective chart review, anonymized data analysis, public database research, surveillance/epidemiological study, humanitarian emergency research, etc.)
2. **Brief Description of the Study:**
   (Provide a summary highlighting objectives, methodology, and populations involved.)

Section C: Justification for Requesting Waiver

Please provide clear and specific responses to the following:

1. **Reasons for Waiver:**
   (Tick all applicable and support with details)
   - Obtaining consent is impracticable for this research (e.g., very large dataset, participants untraceable, retrospective nature).
   - Data/sample is completely anonymized/de-identified.
   - Research presents no more than minimal risk to participants.

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- No direct contact or intervention with participants is anticipated.
- Public health surveillance/epidemic or emergency setting where consent is not feasible.
- Other—please specify:

Details/Elaboration:
(Justify each box ticked above; provide scientific and ethical rationale.)

2. **Potential Impact on Participants:**
   - Describe any potential risks and why the waiver will not adversely affect participant rights and welfare.
3. **Plans for Additional Information (if any):**
   - Will participants be provided information after participation, where applicable? Describe how.

Section D: Confidentiality and Data Protection

1. **Describe methods for anonymization/de-identification of data/samples:**
2. **Measures to ensure privacy and confidentiality:**
3. **Duration and method of data retention/storage:**
4. **Access and use limitations during and after the study:**

Section E: Compliance and Regulatory References

- **Does the waiver meet conditions as per Section 5.7 ICMR National Ethical Guidelines (2017)?**
  (Refer to attached guidelines; e.g., minimal risk, impracticability, public benefit, etc.):
- **Relevant legal or policy citations, if any:**

Section F: Supporting Documents (to be attached)

- Study protocol (with section referencing waiver request)

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- Participant information sheet (if applicable)
- Details of anonymization process
- Other relevant supporting documents

Section G: Investigator Declaration

I/we hereby declare that, to the best of my/our knowledge and belief:

- The above information provided is true and complete.
- The request for waiver of consent complies with all institutional and national ethical guidelines.
- I/we will provide additional relevant information to the IEC or participants if circumstances change.

Name & Signature of Principal Investigator:
Date:

Section H: IEC Office Use Only

- Date of IEC Review:
- IEC Decision: [ ] Approved [ ] Not Approved [ ] More information required
- IEC Comments/Conditions (if any):

Name & Signature of IEC Chairperson/Member Secretary:
Date:

Note:
Waiver of consent can only be granted if all regulatory and ethical criteria are strictly met. All correspondence and documentation related to the waiver shall be retained as per SOP and regulatory standards.

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19. FORM – 18 – Appeal or Complaint Form

APPEAL OR COMPLAINT FORM

Section 1: Applicant Information

Field	Details to Provide
Name of Complainant/Appellant	
Affiliation (if any)	
Contact Address	
Email	
Phone Number	

Section 2: Type of Submission

Please tick (✓) the relevant option:

- Appeal against Ethics Committee Decision
- Complaint about an Approved Study
- Complaint Related to Participant Rights/Safety
- Complaint about EC Procedure/Conduct
- Other (please specify): _____

Section 3: Details of Appeal or Complaint

Title of Project/Subject (if relevant):

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Principal Investigator (if relevant):

Ethics Committee Reference Number (if available):

Date of EC Decision/Incident:

Nature of Appeal/Complaint:
(Describe the concern, decision being appealed, or the issue with as much detail as possible. Attach additional sheets if needed.)

Section 4: Evidence/Attachments

(List and attach any supporting documents, correspondences, or other material relevant to the appeal/complaint.)

Description of Attachments

Section 5: Desired Outcome/Relief Sought

(Specify what resolution or action is being requested.)

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Section 6: Declaration

I hereby declare that the information provided above is true to the best of my knowledge. I understand that the Ethics Committee may contact me for further information and that my confidentiality will be maintained as per EC SOP.

Name	Signature	Date

Instructions:

- Submit this form to the Member Secretary, IEC Office (physical or official email).
- All complaints and appeals will be acknowledged, logged, investigated, and decided as per EC SOP.
- The outcome will be communicated in writing.

For Office Use Only

Received by	Date Received	Reference Number

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20. FORM – 19 – Guest/Observer Request Form

GUEST/OBSERVER REQUEST FORM

SECTION 1: Applicant Details

- **Full Name:** _____
- **Designation/Role:** _____
- **Department/Organization:** _____
- **Contact Address:** _____
- **Phone Number:** _____
- **Email ID:** _____

SECTION 2: Nature of Request

- **Type of Attendee:**
  - ☐ Guest
  - ☐ Observer
  - ☐ Trainee/Prospective Member
  - ☐ Auditor/Regulatory Authority/Accreditation Representative
  - ☐ Invited Expert
  - ☐ Other (please specify): _____

SECTION 3: Meeting Details

- **Date of Requested IEC Meeting:** ___ / ___ / _____
- **Purpose of Attendance:**
  (Briefly specify the reason for attending, e.g., training/learning, audit, accreditation, official visit, etc.)

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SECTION 4: Confidentiality & Undertaking

- I hereby acknowledge that I will not participate in discussions, express opinions, or partake in decision-making unless specifically invited by the Chairperson.
- I agree to **maintain strict confidentiality** regarding all meeting contents, deliberations, and documents reviewed or discussed during my attendance, as per IEC SOPs and institutional policy.
- I will not copy, retain, share, or disseminate any IEC materials or information outside official IEC business.
- I understand that violation of confidentiality may lead to removal from the meeting and further actions as per institutional policy.

Signature: _____ **Date:** ___ / ___ / _____

SECTION 5: For IEC Office Use Only

- **Request Received On:** ___ / ___ / _____
- **Reviewed by (Chairperson/Member Secretary):** _____
- **Decision:**
  ☐ Approved
  ☐ Not Approved
  ☐ Deferred
  (Specify any conditions/restrictions for attendance)

- **Reason / Comments:**

- **Signature (Chairperson/Member Secretary):** _____
- **Date:** ___ / ___ / _____

Guest/Observer to sign Attendance Register and Confidentiality Undertaking prior to start of meeting.

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21. FORM – 20 – Study File/Archive Log

STUDY FILE/ARCHIVE LOG

Section 1: Study Log

Study Identifier/Protocol No.	Title of Study	Principal Investigator (PI)	Dept./Unit	Date File Opened	Date of EC Approval	Date Closed	Archive Location/Box No.

Section 2: File Movement/Archiving Log

Date	Action	Description/Reason	By Whom	Checked Out By	Returned (Y/N)	Date Returned

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22. FORM – 21 – Monitoring Visit Report

MONITORING VISIT REPORT

1. Administrative Details

- **Study Title:**
- **EC Approval Number & Date:**
- **PI (Principal Investigator):**
- **Department:**
- **Study Site:**
- **Date of Monitoring Visit:**
- **Visit Number (Initial/Follow-up):**
- **Names & Designations of EC Representatives/Monitors:**
- **Time of Arrival & Departure:**

2. Purpose and Type of Visit

- ☐ Routine (Scheduled) Monitoring
- ☐ For-cause (Trigger/Complaint)
- ☐ Close-out Monitoring
- **If For-cause, specify reason/complaint:**

3. Site Personnel Present

Name	Role/Designation	Contact

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4. Documents Reviewed

- EC Approval Letter(s)
- Study Protocol (Current, Approved Version)
- Informed Consent Documents (English & Local Languages)
- Participant Information Sheets
- Ethics Committee Correspondence
- SAE/AE Reports
- Protocol Deviations/Violations
- Investigator's Brochure/Product Info
- Study-related Case Record Forms (CRFs)
- Progress Reports/Annual Reports
- Study Logs (Consent, Screening, Enrollment, Drug Accountability, etc.)
- Study-related Training/Delegation Logs
- Confidentiality, COI & Training Declarations
- Other (Specify): _____

5. Physical Facilities Assessment

- Storage and Security of Study Documents [ ] Adequate [ ] Inadequate
- Drug/Device Storage (if applicable) [ ] Adequate [ ] Inadequate [ ] Not Applicable
- Data Protection Measures [ ] Adequate [ ] Inadequate
- Privacy Arrangements for Consent and Procedures [ ] Adequate [ ] Inadequate
- Any observations/deficiencies: _____

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6. Informed Consent Process

- Was the consent procedure as per EC-approved process? [ ] Yes [ ] No
    - If No, details: _____
- Witness/Impartial Observer documentation (if required): [ ] Present [ ] Not Present [ ] NA
- Audio-visual consent recorded (if applicable): [ ] Yes [ ] No [ ] NA

7. Enrollment and Study Status

- Number of participants screened: _____
- Number enrolled: _____
- Number completed: _____
- Number withdrawn/discontinued: _____
    - Reason(s) for withdrawal (if any): _____

8. Protocol Adherence

- Any protocol deviations/violations noted: [ ] Yes [ ] No
    - If Yes, describe: _____
- Compliance with approved protocol: [ ] Satisfactory [ ] Requires improvement

9. Safety Monitoring

- Serious Adverse Events (SAE) reported: [ ] Yes [ ] No
    - Number: _____
    - Timely reporting to EC: [ ] Yes [ ] No
    - Management and follow-up documented: [ ] Yes [ ] No
- Adverse Events (AE) documented: [ ] Yes [ ] No

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- Review comments: _____

10. Participant Welfare

- Assessments of protection of participant rights/welfare: [ ] Satisfactory [ ] Concerns Noted
- Participant complaint mechanism displayed: [ ] Yes [ ] No
- Any participant complaints received: [ ] Yes [ ] No
  - If Yes, summary and action taken: _____

11. Investigator & Team Compliance

- GCP/Research Ethics Training Certificates available: [ ] Yes [ ] No
- PI/Team familiar with protocol, EC requirements, SOPs: [ ] Yes [ ] No
- All team delegation/training logs updated: [ ] Yes [ ] No

12. Recommendations/Action Points

- Summary of key findings:
- Corrective actions suggested (attach additional sheet, if required):
- Timeline for compliance:

13. Overall Assessment

- ☐ Satisfactory (No major issues)
- ☐ Minor issues (Attach details, require follow-up)
- ☐ Major issues (Immediate action required; report to EC Chair/Dean)

14. Monitor's Declaration

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We hereby confirm that this monitoring visit was conducted in accordance with institutional SOPs and national ethical guidelines.

Name of Monitor(s)	Signature(s)	Date

Submit completed Monitoring Visit Report to:
Member Secretary, Institutional Ethics Committee
Manubhai Patel Dental College & Hospital

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