STANDARD OPERATING PROCEDURES

FOR

"Institutional Ethical Committee – Chhattisgarh Dental College & Research Institute"

Chhattisgarh Dental College & Research Institute
G.E. Road, Vill-Sundra, Rajnandgaon – 491441 (C.G.)

Standard Operating Procedures for Institutional Ethical Committee, Chhattisgarh Dental college & Research Institute, Rajnandgaon

S. No.	Name	Designation	Signature	Date
Prepared By	Dr. Pramod Kumar	Prof. & HOD Department of Oral Pathology & Microbiology		01/08/25
Reviewed by	Dr. Suraj Multani	Prof. & HOD Department of Public Health Dentistry		01/08/25
Approved By	Padma Shri Dr. Pukhraj Bafna	Private Practitioner Chairperson, IEC, CDCRI		01/08/25

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Contents

Abbreviations used in Standard Operating Procedure

1.	AIDS	Acquired Immuno Deficiency Syndrome
2.	CDCRI	Chhattisgarh Dental College & Research Institute
3.	COI	Conflict of Interest
4.	CTA	Clinical Trial Agreement
5.	CV	Curriculum Vitae
6.	DSMB	Data and Safety Monitoring Board
7.	GCP	Good Clinical Practice
8.	HIV	Human Immuno deficiency Virus
9.	HMSC	Health Ministry's Screening Committee
10.	ICD	Informed Consent Document
11.	ICMR	Indian Council of Medical Research
12.	IEC	Institutional Ethical Committee
13.	LAR	Legally Authorized Representative
14.	MoU	Memorandum of Understanding
15.	NGO	Non-Governmental Organization
16.	PI	Principal Investigator
17.	SAE	Serious Adverse Events
18.	SOP	Standard Operating Procedure
19.	TOR	Terms of Reference

1. Introduction:

Medical research is the cornerstone of advancing healthcare, driving discoveries that improve diagnosis, treatment, and prevention of diseases. Medical research, also known as biomedical or health research, involves the systematic study of human health and disease using scientific methods. Over the decades, medical research has led to groundbreaking innovations such as gene therapy, stem cell treatments, advanced cancer therapies, vaccines, and organ transplantation techniques

Supervision and regulation of the entire process by qualified professionals is essential to any research project in order to uphold the highest standards. In order to accomplish this, our Institute has developed the following rules, which will be referred to as Standard Operating procedures (SOPs) and both researchers and IEC members must strictly abide by the principles stated in it.

2. Adoption of SOP

Chhattisgarh Dental College & Research Institute, Rajnandgaon herein after referred to as "CDCRI" has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioural research conducted at CDCRI.

3. Objectives of SOP

The objective of this Standard Operating Procedures of the Institutional Ethical Committee (IEC) of CDCRI is to maintain effective functioning of the CDCRI-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

4. Authority for constituting the CDCRI-IEC

The Dean in consultation with the Director, CDCRI will appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter (Annexure 1A & 1B). Members will confirm their acceptance to the Dean by providing all the required information for membership (Annexure 2). The Chairperson will furnish any information or report to the Dean of Faculty, CDCRI when required.

5. Composition and Requirements of CDCRI – IEC

A. Composition of IEC

i. ECs should be multi-disciplinary and multi-sectoral.

ii. There should be adequate representation of age and gender.

iii. Preferably 50% of the members should be non-affiliated or from outside the institution.

iv. The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.

v. The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

The composition, affiliations, qualifications, member specific roles and responsibilities are given in Table below.

Table: Composition, affiliations, qualifications and role & responsibilities of members of ethical committee.

S. No.	Members of EC	Qualification	Role and Responsibilities
1.	Chairperson (Non-affiliated)	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. • 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 (Affiliated)	• Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good	• 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.

		communication skills. • Should be able to devote adequate time to this activity which should be protected by the institution	• 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. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
3.	Basic Medical Scientist(s) (Affiliated/Non Affiliated)	• 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)	• Should be an 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)	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• 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 guidelines etc. • Interpret and inform EC members about new regulations if any.
6.	**Social scientist/ philosopher/** ethicist/theologian (Affiliated/ non-affiliated)	• 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)	• 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	• Ethical review of the proposal, IC 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.

		moral values of the community • Desirable: involved in social and community welfare activities	

vi. So as to maintain independence, the head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

vii. The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

viii. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

ix. The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.

x. The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.

xi. As far as possible a separate scientific committee should priorly also review proposal before it is referred to EC. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

B. <u>Criteria for selection of members of an EC</u>

i. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.

ii. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

C. Requirements for EC members: Every EC member must:

i. Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable.

ii. Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);

iii. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;

iv. Be aware of relevant guidelines and regulations;

v. Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;

vi. Sign a confidentiality and conflict of interest agreement/s;

vii. Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and

viii. Be committed and understanding to the need for research and for imparting protection to research participants in research.

6. Term of reference of IEC members

1. The head of the institution should appoint all IEC members, including the Chairperson.
2. The appointment letter issued to all members should specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following:
   - Role and responsibility of the member in the committee.
   - Duration of appointment.
   - Conditions of appointment.
3. Generally, the term of IEC membership may be 5 years. The duration could be extended with the prior permission of head of the institute and chairman IEC.
4. As specified in the SOPs. A defined percentage of IEC members could be changed on a regular basis.
5. Members to be appointed on the IEC should be willing to fulfil the IEC requirements as mentioned above.

Roles and responsibilities of the IEC

i. The basic responsibility of an IEC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

ii. The IEC must ensure ethical conduct of research by the investigator team.

iii. The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

iv. The IEC 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.

v. The IEC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

vi. The IEC 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.

vii. Responsibilities of members should be clearly defined. The SOPs should be given to IEC members at the time of their appointment.

viii. The chairperson should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

ix. The IEC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

x. The IEC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

xi. The IEC should recommend appropriate compensation for research related injury, wherever required.

xii. The IEC should carry out monitoring visits at study sites as and when needed.

xiii. The IEC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

xiv. The IEC 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.

Types of research proposals reviewed under Biomedical and Health Research

i. Clinical Research
ii. Clinical Drug Trials
iii. Diagnostic trial
iv. Observational studies
v. Clinical pharmacology research
vi. Epidemiological studies
vii. Interventional studies

IEC, CDCRI will be reviewing the research proposal of Chhattisgarh Dental College & Research Institute, Rajnandgaon only and **not from outside the institutions.**

7. Condition of appointment and quorum requirement

A. Conditions of appointment

i. A member should be willing to reveal his / her full name, profession, and affiliation; all reimbursement for work and expenses (if any), within or related to the Committee as these details will be made available to the appropriate authority upon request.

ii. A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

iii. Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences.

B. Quorum requirements

i. A minimum of five members present in the meeting room.

ii. The quorum should include both medical, non medical or technical or/and non-technical members.

iii. Minimum one non-affiliated member should be part of the quorum.

iv. Preferably the lay person should be part of the quorum.

v. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

vi. No decision is valid without fulfilment of the quorum.

vii. All decisions will be taken in meetings and not by circulation of project proposals.

viii. Quorum will have 5 members with following representations:

1. Basic medical scientists.
2. Clinician
3. Legal expert
4. Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
5. Lay person from the community.

8. Procedure for resignation, replacement or termination of members

A. Resignation/replacement procedure

i. A member can tender resignation from the committee with proper reasons to do so.

ii. In case of inability to attend the meeting, members are contacted personally or telephonically and if they wish to rescue themselves, they are allowed to do the same with prior permission of the Chairman/ member secretary.

iii. The members who have resigned may be replaced at the discretion of the DEAN, CDCRI, Rajnandgaon in consultation with Chairman, IEC.

iv. IEC members who decide to withdraw must provide Chairman/Member Secretary, the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.

v. In case of resignation, the Dean will appoint a new member in consultation with the Chairman, falling in the same category of membership ex. Basic Medical Scientist will be replaced with Basic Medical Scientist or legal expert will be replaced with another legal expert, although recommendations may be sought from the resigning member.

vi. Appointment may be made with joint consultation of the Member Secretary and the chairman.

vii. In case of new appointment of a member, the procedure as described earlier for constitution of IEC will be adopted.

B. Policy for removal of member

i. A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the Ethics Committee.

ii. Inability to participate in the meetings on any grounds for more than 3 meetings of the IEC.

iii. The membership shall be reviewed by the Dean and Chairperson, if the member is a regular defaulter.

iv. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairperson IEC for necessary action.

v. In all such circumstances, Dean will serve a letter of termination to the member on the recommendation of Member secretary.

vi. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting.

The current tenure of existing EC members is of 5 years from the date of appointment.

9. Training

a. All the ethical committee members should be trained in human research protection, applicable EC SOPs, and ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, GCP guidelines and relevant regulations of the country.

b. EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented.

c. Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members.

d. EC members should be aware of local, social and cultural norms and emerging ethical issues.

e. The members should update their knowledge on ethics by attending various courses and training program on ethics once during the tenure of IEC.

10. **Conflict of interest:** Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.

Identifying, mitigating and managing COI:

The broad responsibilities of those involved in research, with respect to COI, are given below:

1. **Research institutions must:**
   - Develop policies and SOPs to address COI issues that are dynamic, transparent and actively Communicated.
   - Implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies.
   - Monitor the research or check research results for accuracy and objectivity.
   - Not interfere in the functioning and decision making of the EC.
2. **Researchers must:**
   - Ensure that documents submitted to the EC include disclosure of COI (financial or non financial) 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.
3. **ECs must:**
   - Evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this.
   - Require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI.
   - Make appropriate suggestions for management, if COI is detected at the institutional or researcher's level.

Conduct of Meeting: Members should assemble in the IEC meeting room at the appointed time. If an IEC member has a conflict of interest related to a project, they should disclose it

before the meeting starts and leave the room before the topic is discussed. This should be recorded in the minutes.

Process of Decision Making: IEC member will withdraw from the meeting for the decision procedure concerning the study where conflict of interest exists. If any IEC member has her/his own proposal for IEC review he/she will not participate in the IEC discussion making or vote on that particular project. Decisions will only be made at meetings where a quorum is present. Neither PI nor any of proposed study team members participated during the decision making of the IEC. Only IEC members who attend the meeting will participate in the decision.

11. Conduct of CDCRI - IEC meetings

The Chairperson will conduct all meetings of the CDCRI-IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/ She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

12. Independent consultants

The CDCRI - IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the CDCRI - IEC.

13. Application procedures

1. All proposals should be submitted on any working day 2 weeks in advance of scheduled meeting in the prescribed application form, the details of which are given under "XII Documentation". The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.
2. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, CDCRI-IEC and Institutional Website www.cdcri.org).
3. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson CDCRI-IEC, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.
4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.
5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be

submitted within a stipulated period of time as specified in the communication or before the next meeting.

6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5%. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non-Profitable Organizations etc.

14. Documentation: All Research proposals (3 copies) shall be submitted in printed copy along with the information and documents as specified in Annexure-3A, 3B and Annexure 4-6.

15. Review procedures

1. All types of biomedical and health research (whether clinical, basic science, policy making, implementation, epidemiological, behavioural, public health research, etc) will be reviewed by an EC before it is conducted.
2. IEC, CDCRI will be reviewing the research proposal of Chhattisgarh Dental College & Research Institute, Rajnandgaon only and not from outside the institutions,
3. The meeting of the IEC will be held on periodic intervals, i.e. 3rd Monday of Jan, March, May, July, Sep, Nov, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
4. The proposals should be sent to the IEC at least 2 weeks in advance of scheduled meeting.
5. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review (as described below).
6. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
7. Researchers will be invited to offer clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.

8. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
9. The decisions will be minuted and Chairperson's approval will be taken.

16. Exemption from review

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

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

Exceptions:

a) When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
b) When interviews involve direct approach or access to private papers.

17. Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve

a) Minor deviations from originally approved research during the period of approval.
b) Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
c) Research activities that involve only procedures listed in one or more of the following categories:

- Clinical studies of drugs and medical devices only when -

i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

d) Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

e) When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

i. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster- affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

viii. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

18. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

i. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:
   - From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week.
   - From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more

than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week.

- From neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

ii. Prospective collection of biological specimens for research purposes by noninvasive means. For instance

- Skin appendages like hair and nail clippings in a non-disfiguring manner;
- Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
- Excreta and external secretions (including sweat);
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization and bronchial lavages.

iii. Collection of data through non-invasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity,

electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,

- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.\

iv. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

v. Collection of data from voice, video, digital, or image recordings made for research purposes.

vi. Research on individual or group characteristics or behaviour not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

19. Aspects considered during review of research proposal:

i. Scientific design and conduct of the study.

ii. Approval by appropriate scientific review committees / Research committee, if any.

iii. Examination of predictable risks/harms

iv. Examination of potential benefits.

v. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues.

vi. Management of research related injuries, adverse events.

vii. Compensation provisions.

viii. Justification for placebo in control arm, if any

ix. Availability of products, benefits to subjects after the study is completed if applicable.

x. Patient information sheet, informed consent form in English and in local languages.

xi. Protection of privacy and confidentiality.

xii. Involvement of the community, wherever necessary

xiii. Plans for data analysis and reporting.

xiv. Adherence to all regulatory requirements and applicable guidelines.

xv. Competence of investigators, research and supporting staff.

xvi. Facilities and infrastructure of study sites.

xvii. Criteria for withdrawal of patients, suspension or premature termination of a study in CDCRI.

20. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision.
2. When consensus is not arrived at, the decision will be made by voting procedure.
3. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
4. Decision will be made only in meetings where quorum is complete.
5. Only the members can make the decisions. The expert consultants will only offer their opinions.
6. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
7. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
8. Modified proposals will be reviewed by an expedited review through identified members.
9. Procedures for appeal by the researchers will be clearly defined.

21. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format. All the approvals will be valid for three years or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.
2. The communication of the decision will include:
    a. Name and address of IEC.
    b. The date, place and time of decision.
    c. The name and designation of the applicant.
    d. Title of the research proposal reviewed.
    e. The clear identification of protocol no., version no., date, amendment no., date.
    f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.

g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
h. A clear statement of decision reached.
i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the CDCRI IEC
j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
l. Signature of the member secretary with date

22. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure-4A, 4B 4C & 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.
8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of investigators/sites must be informed to the office of IEC.

10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
11. Applicant must inform the time of completion of study and must send the result summary to IEC.
12. IEC must receive a copy of final summary of study completed from the applicant

23. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

1. The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.
2. Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.
3. In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;
4. Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethical committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of

death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethical Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event. (See Annexure 8).

5. In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.
6. The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s)

1. The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority, the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethical committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethical committee and Chairman of the Expert Committee constituted by the Licensing authority with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethical Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

2. The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

24. Record keeping and archiving at the office of CDCRI

1. All the documents and communications of IEC will be numbered, dated, filed and archived in a secure place.
2. Only the member secretary or persons authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except meeting agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the CD or DVD containing all the research proposals and other related documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.
6. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of CDCRI – IEC.
    b. Curriculum Vitae (CV) of all members of CDCRI - IEC with records of training in Human ethics if any.
    c. Standard Operating Procedures of CDCRI - IEC.
    d. Annual report
    e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
    f. The published guidelines for submission established by the EC.
    g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
    h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.

i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.

j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.

k. Record of all notification issued for premature termination of a study with a summary of the reasons.

l. Final report of the approved projects, including microfilms, CDs and Video recordings.

25. Updating CDCRI - IEC members

1. All relevant new guidelines should be brought to the attention of the members.
2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

26. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

Individuals may be considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited;
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

The key principle to be followed when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.

Principles of research among vulnerable populations

- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
- Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

Obligations/duties of stakeholders

All stakeholders have different responsibilities to protect vulnerable participants.

Stakeholders	Obligations/ Duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures to ensure a balanced benefit-risk ratio • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations
Ethics Committee	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits.

	• Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

Annexure 1 A

Letter Ref. No: Date:

From

Dean, CDCRI, Rajnandgaon

To,

_____

_____

Sub: Constitution of Institute Ethics Committee (Human studies) - Reg.

Dear Sir / Madam,

On behalf of Chhattisgarh Dental College & research Institute, Rajnandgaon an affiliated Institute by Pt. Deendayal Upadhyay Memorial Health Sciences and Ayush University of Chhattisgarh, Raipur and by Dental Council of India, New Delhi, I request your concurrence for possible appointment as a member of Institute Ethics Committee of CDCRI, Rajnandgaon. Kindly send your written acceptance in the enclosed format and provide short curriculum vitae along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Annexure 1 B

APPOINTMENT ORDER

Dr/ Mr. / Mrs.: Date:

I am pleased to appoint you as _____ of the Institutional Ethics Committee (IEC) (Human research) at Chhattisgarh Dental College & Research Institute, Rajnandgaon w.e.f. _____ for a term of _____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, CDCRI.

We sincerely hope your association with IEC, CDCRI will be fruitful to the Institute & the Community we serve.

Signature and seal

Dean

Annexure 2

Membership Consent Letter

From,

_____

_____

To
The Dean
CDCRI
Rajnandgaon-491441

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg.

Ref: Your Letter No: _____ dated:_____

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of CDCRI, Rajnandgaon. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature

Name of the Member Date:
Address:

Telephone No: (Off) (Res) email:

Annexure 3 A

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Guide in case of thesis proposals.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug / device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
9. Usefulness of the project / trial
10. Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any
11. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
12. Agreement to report all Serious Adverse Events (SAE) to CDCRI -IEC.
13. Other financial issues including those related to insurance.
14. An account of storage and maintenance of all data collected during the trial.
15. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Statement of conflicts of interest, if any.
18. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
19. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided

20. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
21. Curriculum vitae of all the investigators with relevant publications in last five years.
22. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
23. Any other information relevant to the study.
24. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 3B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF CDCRI, Rajnandgaon

Submit three (3) hard copies of the Research Proposal along with Covering letter and 'soft copy' along with the following information to the Member Secretary, Institution Ethics Committee at the IEC office, CDCRI.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee. All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given,** before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible ***on third Monday*** of Jan, March, May, July, September, and November. The frequency will change depending upon the number of proposals.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

The format of submission of research synopsis should be according to forms as mentioned in SOP Version 2. Annexure 3B.

Annexure 4 A

Chhattisgarh Dental College & Research Institute, Rajnandgaon
Ethics committee
Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details. including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 4 B

Chhattisgarh Dental College & Research Institute, Rajnandgaon
Institutional Ethical Committee

Format for submission of revised/additional documents, protocols and information regarding already approved projects to be submitted by the Principal Investigator (PI)

(Two copies of this form along with the revised documents to be submitted)

1. **IEC Reference No:**

2. **Approval Date and Number:**
3. **Title:**

4. **Principal Investigator:**

5. **Purpose of this submission:**

6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:

Signature PI:

Date:

Name:

Annexure 5

Chhattisgarh Dental College & Research Institute, Rajnandgaon

Institutional Ethical Committee

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in English or regional language, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points:

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

Annexure 6

Chhattisgarh Dental College & Research Institute, Rajnandgaon
Institutional Ethical Committee
PARTICPANT INFORMED CONSENT FORM (PICF)

Protocol Study number: _____
Patient identification number for this study: _____
Title of the project: _____
_____

Name of Principal investigator: _____**Tel. No (s).:** _____
The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.
The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected.
I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from CDCRI.

I give permission for these individuals to have access to my records. I agree to take part in the above study.

Date:
Place: **Signatures / Left Thumb Impression)**

Name of Participant: _____**Son/Daughter/spouse of:** _____
Complete postal address: _____
This is to certify that the above consent has been obtained in my presence.

Date:
Place: **Signatures of the PI**

Witness – 1

Signature
Name:
Address:

Witness – 2

Signature
Name:
Address:

Note: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution
(Investigators are advised to prepare the translation in simple understandable Hindi on their own)