Government Dental College, Rajabandha Maidan, Raipur, Chhattisgarh, India

Institutional Ethics Committee

For Research on Human Subjects

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Standard Operating Procedures

(SOPs)

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(As per recent regulatory requirement and requisite of accreditation)

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Introduction

Government Dental College, Raipur, Chhattisgarh, India(GDC, Raipur) is an autonomous institute under the Department of Health & Family Welfare and Medical Education, Government of Chhattisgarh, established for Dental education, research, and patient care especially in state of Chhattisgarh. The college caters UG course, PG courses and Patient's dental care. One of the objectives of the institute is research in various branches of Dental sciences involving human subjects. The issues of ethics arises when there is involvement of human beings in research. Institutional Ethics Committee is required to be constituted in every such institute to ensure the ethical practices by the researchers. All research in human subjects is now guided by principle given in the declaration of Helsinki. This is also the basis of Good Clinical Research Practices (GCP) adopted by the International Conference on Harmonization (ICH). The Indian Council of Medical Research (ICMR) has also issued ethical guidelines for research on human subjects. This, also, forms a part of GCP guidelines issued by Central Drug Standard Control Organization (CDSCO) of Ministry of Health, Government of India. Putting into practice these principles, a standard operating procedure is formulated for functioning of institutional ethics committee (IEC).

1. Name of the Ethics Committee

This Ethics Committee may be called as "Institutional Ethics Committee, Government Dental College, Raipur" , in short IEC, GDC, Raipur.

2. Scope and Objectives

The SOP applies to the functioning of all activities under the IEC of GDC, Raipur. This includes the basic responsibilities of the IEC, composition, appointment of the members and conduct of the meeting to review the research related to health and biomedical field involving human subjects.

The objective of Standard Operating Procedure (SOP) is to ascertain a quality and consistent ethical review mechanism for research proposals related to health and biomedical research on human subjects following the contemporaneous ICMR and national ethical guidelines. IEC will review and approve all types of research proposals involving human subjects with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and wellbeing of the research subjects/participants. The IEC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, the IEC will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. IEC will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IECs will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

3. Authority under which IEC is constituted:

The IEC shall be constituted under the Principal, Government Dental College, Raipur as per ICMR and other regulatory guidelines for human research.

4. Constitution and Composition of IEC

a. Constitution of IEC

I) IEC should be constituted in the following pattern:

i). A Chairperson
ii). A Deputy Chairman, if need, will be among the member of the committee.
iii). A Member Secretary,
iv). 6– 8 members from different Departments / Specialties / disciplines or areas etc

II) Process of constituting IEC-GDC Raipur

i). Chairperson and Member Secretary for IEC- GDC Raipur will be nominated by the Principal, GDC, Raipur with due consultation of college council of GDC, Raipur.
ii). The IEC will be constituted by the Principal, GDC, Raipur in consultation with the Chairperson of the IEC.
iii). The Principal, GDC, Raipur will invite the members to join the IEC by sending the official request letter (Annexure - 1).
iv). Members will confirm their acceptance to the Principal, GDC, Raipur by providing all the required information for membership (Annexure - 2)
v). A formal appointment orders (Annexure - 3) will be sent to members of IEC by The Principal, GDC, Raipur after the receipt of their acceptance and agreement of confidentiality (Annexure -4).
vi).The Principal, GDC, Raipur will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve. The Principal, GDC, Raipur instruct Chairperson of IEC to conduct the regular proceedings of the IEC for the college and will review the functioning of IEC regularly.

b. Composition of IEC

i). IECs shall be multidisciplinary and multi-sectorial in composition.
ii). The number of members in the committee shall be kept small (7-11 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. The external members shall be in majority to ensure the independence of the committee.
iii)The Chairperson of the committee shall be from outside the Institution and not former Principal /former Head of GDC, Raipur. The Member Secretary, drawn from GDC, Raipur itself, shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoint
iv)The composition may be as follows:-

1. **Chairperson-** Non-affiliated member
2. **Basic medical scientists**- Non-affiliated member
3. **Clinicians**- Affiliated / Non-affiliated member
4. **Legal expert-** Affiliated / Non-affiliated member, reputed lawyer / retired judge
5. **Social scientist/representative of non-governmental voluntary agency/philosopher** - Non-affiliated member
6. **Educated person from the community**- Non-affiliated member
7. **Member-Secretary**- Affiliated member

v). IEC shall have majority of its members from other institutions(Non-affiliated). They could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age , community etc. in the Committee to safeguard the interests and welfare of all sections of the society.

5. Terms of Reference for IEC and IEC Members

Terms of reference entails the working of IEC in reference to its members and will be maintained in the office of IEC. It includes -

a. Requirements of membership
b. Terms of Appointment of the members with reference to the duration of their term,
c. The policy for removal, replacement and resignation procedure
d. Frequency of meetings
e. Payment of processing fee to the IEC for review
f. Honorarium/ consultancy to the members/ invited experts etc.

I. Terms of reference (TOR) for EC

i). The EC must be registered with the relevant regulatory authorities, for example, ECs approving clinical trials under the ambit of Drugs and Cosmetics Act should be registered with CDSCO.

ii). The TOR for the EC and its members should be clearly specified by the institution in the EC SOPs

iii). EC must have a written SOPs prepared as per ICMR guidelines for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority. The SOPs should be updated periodically to reflect changing requirements. A copy of the latest version of SOPs should be made available to each member and they should be trained on the SOPs. The SOPs must be available in the secretariat of the EC as both hard and soft copies. The scope, tenure and renewal policy of the EC should be stated.

iv) IEC of GDC, Raipur will only review the academic research involving human beings submitted by the faculties and Post graduate/ Undergraduate students under the faculty's guidance of the Government Dental College, Raipur. However in future , if Academic College Council of GDC, Raipur decides to include the review of proposals from outside nearby institution, the institution wish to utilize the services of IEC,GDC, Raipur must fulfil the following criteria-

a. The user institution shall make a request to IEC,GDC, Raipur (host institute) and shall enter into an MoU for utilizing the services of the IEC,GDC, Raipur with due permission of host institute authorities.
b. The user institution shall provide a 'No Objection Certificate' and agree to be overseen by the EC of the host institute.
c. The EC of the host institution shall have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.
d. The EC of the host institution can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institute.

The further necessary Criteria must be included in the SOP of IEC GDC, Raipur as per then ICMR and CDSCO Guidelines. The fee for review of the outside proposals will also be decided by the Academic College Council, GDC, Raipur as per then existing Guidelines and will remain clearly mentioned in the MoU signed.

iv). The term of appointment of members could be extended for another term based on his/ her contribution and performance and a defined percentage of members could be changed on regular basis . Preferably, persons trained in bioethics and conversant with ethical guidelines and laws of the country shall be appointed as member of IEC. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances

v). For multicentric biomedical and health research, all participating sites will decide to utilize the services of one common EC from a participating site identified as designated main EC for the purpose of primary review. This EC should be located in India and registered with the relevant authority. However, the local site requirements, such as informed consent process, research implementation and its monitoring can be performed by the local EC. This would require good communication and coordination between the researchers and EC secretariats of participating sites. For clinical trials under the Drugs and Cosmetics Act, the requirements as stated by CDSCO must be followed.

vi). Stem cell proposals should be reviewed and approved by the institutional committee for stem cell research (IC-SCR) before being submitted to the EC for consideration, in accordance with the National Guidelines for Stem Cell Research (2017).

vii). A subcommittee for SAEs review and expedited reviews shall be constituted comprising Member Secretary and two appropriate designated members out of which one should preferably be pharmacologist / basic medical scientist from the main EC . These subcommittees can report to the concerned main EC.

II. Terms of reference for EC Members

i) Head of institute will appoint the Chairperson and EC members with consultation of institutional/College academic council.

ii) The head of institute will issue appointment letters to all EC members specifying role and responsibilities of the member in committee, duration of appointment and conditions of appointment.

iii) Members of the EC should not have any known record of misconduct.

iv) The appointed EC members should tender a written consent indicating willingness to fulfil following EC requirements –

a. To provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines.
b. 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 .
c. Having willingness to undergo training or update their skills/knowledge during their tenure as an EC member.
d. Must sign a confidentiality and conflict of interest agreement/s;
e. No objection to place her/his full name, profession and affiliation to the EC in the public domain
f. Be aware of relevant guidelines and regulations;
g. Ready to understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
h. Committed and understanding to the need for research and for imparting protection to research participants in research.

6. Membership requirements, Condition & Duration of appointment and Honorarium for members :

A. Condition of appointment

Chairperson, Member Secretary, all the Members and Independent Consultants are appointed to the IEC under the following conditions:

- Willingness to abide by the requirements laid in the SOP
- Willingness to publicize his/her full name, profession, and affiliation to public domain
- Willingness to undergo training or update their skills/knowledge during their tenure as an EC member
- All financial accountability, reimbursement for work and expenses, if any, within or related to the IEC should be recorded and made available to the public upon request;
- All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants and related matters
- All members should maintain absolute confidentiality of all discussions during the meetings and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.

B. Membership requirements

All members should fulfil the eligibility criteria as mentioned in National Ethical Guidelines For Biomedical and Health Research Involving Human Participants-2017 and CDSCO guidelines viz.

i). Chairperson/ Vice Chairperson - Non-affiliated member
A well-respected person from any background with prior experience of having served/ serving in an EC.

ii). Member Secretary/ Alternate Member Secretary – Affiliated member,
Should be a staff member of the institution and have knowledge and experience in clinical research and ethics, be motivated and have good communication skills . He should able to devote adequate time for this activity under protection of the institution/ college.

iii). Basic Medical Scientist(s) - Non-affiliated/ Affiliated member
Non-medical or medical person with qualifications in basic medical sciences preferably be a pharmacologist

iv). Clinician(s) – Non-affiliated/ Affiliated member
An individual/s with recognized medical/dental qualification, expertise and training

v). Legal expert/s – Non-affiliated member
Should have a basic degree in Law from a recognized university, with experience if possible have Training in medical law.

vi). Social scientist/ philosopher/ ethicist/theologian - Non-affiliated/ Affiliated member
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

vii). Lay person(s)/Educated person from Community-
Literate person from the public or community and not pursued a medical science or health related career in last 5years .May be a representative of the community from which the participants are to be drawn and aware of the local language, cultural and moral values of the community. Involvement in social and community welfare activities is desirable.

C. Duration of appointment, resignation and replacement

i). The duration of appointment will be initially for a period of 3 years .At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.
ii). A member can be replaced in the event of death or long-term non availability or for any action not Commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
iii). A member can tender resignation from the committee with proper reasons to do so.
iv). IEC members ,who wish to resign, must provide a written notification of their proposed resignation date at least 30 calendar days prior of the next scheduled meeting to Chairperson/ Member secretary.
v). In case of resignation or removal of a member as per rule described in section-8 of this SOP, the Principal, GDC, Raipur will appoint a new member in consultation with the Chairman, falling in the same category of membership ex. Basic Medical Scientist with Basic Medical Scientist.
vi). Recommendations may be sought from the resigning member.
vii). Appointment may be made with joint consultation of the Member Secretary and the Chairman
viii). In case of new appointment of a member, the procedure as described in section 4.(II) of constitution of IEC- GDC, Raipur will be adopted.

D. Honorarium/ consultancy to the members/ invited experts

i). Non-affiliated member will be given a reasonable honorarium decided by the Academic College Council of GDC, Raipur and will be revised time to time
ii). The Invited experts will also be entitled to receive same honorarium as non-affiliated members as and when they invited to participate in the EC meetings.

7.Roles and Responsibilities of committee members:

I). Chairman:

i). The Chairman will be responsible for conducting committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
ii). The Chairman will sign documents and communications related to IEC functioning.
iii). In case of anticipated absence, the Chairman will nominate a committee member as Acting Chairman and he will have all the powers of the Chairman for that meeting
iv).Ensure quorum of meetings, COI declaration from all members, active participation of all members in all discussions and deliberations and fair decision making.
v). Affirm minutes of previous meeting and resolves the complaints against EC members, researchers and issues of conflict of interest, if any.
vi) Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data.

II). Member Secretary:

i). To accept research study/project proposals.
ii). To prepare, maintain and distribute of study files.
iii). To schedule and organize IEC meetings after consultation with Chairman
iv).To prepare and maintain meeting agenda and minutes.
v).To maintain IEC record and to archive them.

vi).To sign documents and communications related to IEC functioning.
vii).To communicate with the IEC members and applicants/ investigators.
viii).To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
ix). To arrange for training of personnel and IEC members.
x). To organize the preparations, review, revision and distribution of SOPs and guidelines.
xi). To provide necessary administrative support for IEC related activities to the Chairman.
xii). To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
xiii). To receive fees and issue official receipts for the same.
xiv). To delegate various responsibilities to appropriate and authorized persons.
xv). To ensure adherence of IEC functioning as per SOPs.
xvi). To ensure training of EC secretariat and EC members as well as updating the SOP as and when required.

III) Joint Member Secretary (whenever appointed):

i). The Joint Member Secretary will assist in function of member secretary or in absence of member secretary perform all the functions of Member Secretary.

IV). Coordinating staff:

i). To support the Member Secretary in executing functions of the IEC.
ii). Correspondence with the IEC members and investigators.
iii). Arranging IEC meetings
iv). Receiving all research proposals
v). Preserving and keeping all the documents related to IEC
vi). Assisting in preparing agenda and minutes of the meetings
vii). To perform any other functions as instructed by Member Secretary/Chairman.

V). IEC members:

i). To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
ii). To review, discuss and consider research proposals submitted for evaluation
iii). To monitor Serious Adverse Event reports and recommend appropriate action(s)
iv). To review the progress reports and monitor ongoing studies.
v). To maintain confidentiality of the documents and deliberations of IEC meetings.
vi). To declare any conflict of interest, if any.
vii). To participate in continuing education activities in biomedical ethics and biomedical research.
viii). To provide information and documents related to training obtained in biomedical ethics and biomedical research or any related activities to the IEC secretariat
ix). To provide an updated CV when requested for by the IEC secretariat
x). To carry out the work delegated by Chairman and Member Secretary / Joint Member Secretary
xi). To assist the Chairman and Member Secretary in carrying out IEC work as per SOP

However, following members should be held responsible for specific activities:

VI). Clinician

i). To provide medical inputs on protocol: Informed consent forms and other aspects like standard of care, Placebo use, Sample size, dosing, Concomitant medications, Prohibited medications, risk & benefit to patients, Age group and Inclusion / exclusion criteria
ii). To take clinical judgement for the trials

VII). Basic Medical Scientist:

i). To provide scientific aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples,
ii). To scrutinize the preclinical data and whether protocol adequately addresses issue of all this matter or not, Qualification of PI and GCP training certificate, Details of SAEs and reporting time limit from PI, all ethics issues and other procedures involved in the study
iii)For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

VIII). Legal Expert:

i). To perform ethical review of the proposal, ICD along with translations , 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 and compliance with guidelines
ii). To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties, contract budget allocation and payment details
iii). To assess the clause for compensation/ treatment in case of incidence of SAE included or not
iv). To inspect whether any clause is violating the norm, Confidentiality, dispute resolution, updated with regulatory requirements and interpretation of the same, Insurance policy: it should cover the participants for injury due to all clauses mentioned in Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit – per person and total
v). Indemnity: it should Covers the liability of investigator and sponsor and Could be part of CTA or separate document
vi). To observe the informed consent document
vii). Interpret and inform EC members about new regulations if any

IX). Social Scientist / NGO representative / Philosopher / Ethicist:

i). To see Community perspective, Informed consent process, Compensation, Design of trial whether it may cause discomfort to subjects, Number of blood samples, Post-trial access to involved community, Confidentiality, Vulnerable population and Recruitment process.
ii) To serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

X).Layperson/Educated person from community

i). To inspect and assess the Informed Consent Process, Trial procedures, Post-trial access, Compensation, Confidentiality, Think from the subject's perspective, No exploitation of subject and Subject diary simple or not.
ii)To evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

8. Procedure for removal of members

A member may be relieved or terminated of his/her membership in case of -
i).Conduct unbecoming for a member of the Ethics Committee
ii). Inability to participate in the meetings on any grounds
iii). If a regular member fails to attend more than 3 meetings of IEC. The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Principal GDC Raipur, by the Chairman IEC for necessary action .
iv). Member relocated to another city or any such matter .
In all such situations/circumstances, Principal, GDC Raipur will serve a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/ roster will be revised.

9.Offices/Conduct of the Meeting

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

10.Quorum Requirements

- A minimum of 5 members including Chairperson of IEC is required for quorum, out of which at least two members should be non-affiliated.
- This quorum must include at least one non-scientific member that may either be a lawyer, philosopher or preferably a lay person from the community.
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- No decision is valid without fulfilment of the quorum.
- All decisions should be taken in meetings and not by circulation of project proposals.

11.Independent Consultation

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

12.Application Procedure

I). All proposals should be submitted in the prescribed application form(annexure -5), in at least 5 copies with cover letter and brief CV of investigators (annexure-6) to the member secretary/ chairman mentioning the type of review requested [Exempt from review/ Expedited review /Full committee review].

II). In case of seeking exemption from review, expedited review, and clinical trial the protocol in prescribed application form must be submitted along with duly filled application form for exemption from review (Annexure-7), application form for expedited review(Annexure-8) and application form for clinical trials(annexure-9)
III). An Undertaking by the Investigator(Annexure-10) must be submitted in case of clinical trial of new drug and device along with research protocol
III). All relevant documents should be enclosed with application.
IV). The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators /Collaborators should be forwarded by the Head of the Department.
V). The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
VI). The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
VII).The decision of IEC 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.

13.Documentation

All research proposals (synopsis of the research)should be submitted with duly filled and signed prescribed initial review application form(annexure -5). Following applicable documents must be attached –

i). Approval of the Head of the Department.
ii). Name of any other Institute/Hospital/Field area where research will be conducted and permission letter of concerned institute with memorandum of understanding.
iii).For multi-disciplinary research involving various departments of GDC, Raipur , the PI would approach HODs of all the departments to obtain collective departmental assent and approval in writing.
iv). Protocol of the proposed research.
v). Ethical issues in the study and plans to address these issues.
vi). Patient information sheet(PIS)(annexure-11) and informed consent form(ICF) in English and Hindi/local language(s) (annexure-12) should be enclosed. The patient information sheet(PIS) should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005). For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country/other countries, if available.
vii). Advertisement, notices for Recruitment procedures
viii). Patient instruction card, diary, etc.
ix). Investigator's brochure (as applicable for drug/biologicals/device trials)
x). Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
xi). Documentation (or plan) of clinical trial registration (preferable)
xii). Brief curriculum vitae (1-2 pages maximum) of all the study researchers (annexure-06)
xiii). Any regulatory (DCGI/CDSCO etc.)clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
xiv). Source of funding and Budget along with the supporting documents.
xv). Indemnity issues including insurance for the compensation to the participants etc.
xvi). An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
xvii). A Statement of conflicts of interest, if any.

xviii). Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
xix). Agreement to submit annual progress report and final report at the end of study.
xx). Approval of scientific committee
xxi). In case the research is proposed in collaboration with an institution or department or centre or any other entity from a foreign country and funds are proposed to be received from foreign collaborator, the appropriate sections (and latest amendments) of Foreign Contributions (Regulation) Act, 2010, where applicable, state the applicability of the provision(s) of FCRA, 2010.
xxii). Material Transfer Agreement (as in collaborative research) where any biological samples are to be transferred from the Institute to other institute or laboratories or other agencies for testing or storage or for any future use.
xxiii). PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).
xxiv). Any other information relevant to the study as per prescribed application form (annexure -5)

14.Processing fee

i) No Processing fee will be levied for all the research proposals which are non-funded studies and departmental studies.
ii). Proposed protocol funded by government agencies like ICMR/UGC/DST, Government of India, State Science & Technology Department and other non-profitable funding agencies like UNICEF, WHO, USAID etc. will be levied 5% processing charges of total budget of project /study for GDC, Raipur.
iii). All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals will be levied 10% processing charges of total budget of project /study for GDC, Raipur.
iv). Processing fees will be handled as per Institutional Protocol.

15.Review Procedure

i). All the research proposals or other communications with IEC will be reviewed following the provisions given in ICMR Guidelines, 2017 and the New Drugs and Clinical Trials Rules, 2019.
ii). Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
iii). The proposals will be sent to members at least 2 weeks in advance. For every proposal, minimum one primary and one secondary reviewers will be identified amongst the IEC members. These reviewers will first scrutinise the submitted documents and enclosures as defined above and will lead the discussion during IEC meeting.
iv). Decisions will be taken by consensus after discussions, and voting will be done if necessary.
v).PI should be available during the meeting and may be invited to offer clarifications.
vii).Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
viii).The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

16. Element of Review

i). Scientific design and conduct of the study.
ii)Approval of scientific review committee and regulatory agencies.
iii). Assessment of predictable risks/harms and potential benefits.
iv). Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
v). Management of research related injuries, adverse events and compensation provisions.
vi). Justification for placebo in control setting, if any.
vii). Availability of products to the trial subjects after the study, if applicable.
viii). Patient information sheet and informed consent form in English/Hindi and local language.
ix). Protection of privacy and confidentiality of subjects.
x). Involvement of the vulnerable individuals/community, wherever necessary.
xi). Protocol and proforma of the study including the consent form.
xii). Plans for data analysis and reporting.
xiii). Adherence to all regulatory requirements and applicable guidelines.
xiv). Competence of investigators, research and supporting staff.
xv). Facilities and infrastructure.

17.Exemption from review

Research protocol submitted by PI seeking exemption from review must include the duly filled application form for exemption from review (annexure-6). The Proposals, which involves less than minimal risk without link identifier, are considered for exemption from review. The conditions may be as follows-

i).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.

ii). Research conducted on data available in the public domain for systematic reviews or meta-analysis.
iii). Quality control and quality assurance audits in the institution.
iv). Consumer acceptance studies related to taste and food quality.
v). Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

18. Expedited Review

Research protocol submitted by PI seeking expedited review must include the duly filled application form for expedited review (annexure- 7). The member secretary of IEC -GDC Raipur , if IEC find that the protocol is eligible for expedited review, may ask the PI to submit duly filled application form for expedited review too.

Research Proposals, which involves no more than minimal risk as per National ethical guidelines for biomedical and health research involving human participants -2017 by ICMR, will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The subcommittee should consist of Chairperson/ member secretary, 1-2 IEC member and preferably 1 external member. However, it is discretion of chairman to authorise a group of member for expedited review. Verification of furnished documents and regulatory clearances can be done at the level of the Member-Secretary. The approvals will be reported in the next IEC meeting by Member Secretary.
Proposals eligible for expedited review are-

i). Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
ii). Research involving clinical documentation materials that are non-identifiable (data, documents, records).
iii). Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
iv). Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
v). Minor deviations from originally approved research causing no risk or minimal risk.
vi). Progress/annual reports where there is no additional risk, for example activity limited to data analysis.
vii). Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.
viii). Multicentre research where a designated main EC among the participating sites has reviewed and approved the study.
ix). Research during emergencies and disasters
x). Cases of nationally relevant proposals requiring urgent review.

19.Full committee review

All research protocols shall be subjected to full review by all the members, which fall under the criteria as follows-

i).Proposal unqualifies for exempted or expedited review.
ii). Protocol involves subjects with more than minimal risk.
iii). Research Proposal includes vulnerable population and special groups.
iv). Research protocol involves deception of participants .
v). Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.
vi). Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk;
vii). Major deviations and violations in the protocol.
viii). Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment.
ix). Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need.
x). Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

20. Review in case of vulnerable population

i). Ethics committee must determine whether the participants for a particular research belongs to vulnerable population group as per ICMR Guidelines 2017 (e.g. children and adolescents, pregnant and lactating women, students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, mentally challenged patients, critically ill patients, suffering from stigmatizing or rare diseases, unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnicminorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), tribals and marginalized communities, refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations etc.) at the time of review of a protocol .
ii). In case of involvement of vulnerable population group, proper justification for inclusion as well as benefit & risk to the participants must be verified by all the IEC members.
iii). Vulnerable group can become participants only if the study is designed to protect or advance the health of this population and for which the non- vulnerable group would not be suitable participants
iv). In case of involvement of vulnerable subjects, the additional precaution should be taken to avoid exploitation retaliation/reward/credits, etc
vi). If there is no medically accepted alternative to the therapy but to involve the children of age group 12-18 year in the trial, consent/ assent has to be obtained from parents/ legal guardian and the language and presentation of the contents in the 'Participant Information Sheets' and the 'Consent/Assent forms' must be in the manner which is understood by a child of 10 years of age .
vii). Rights and welfare of people who are unable to give informed consent must be protected. Informed consent should be obtained from legally accepted representatives (LAR) in the presence of impartial witness with adequate explanation of risks and benefits.
viii). The privacy , confidentiality and rights of the vulnerable subjects must be protected at all the times -during research and even after completion of study
ix). Only full committee initial and continuing review of such proposals shall be performed and committee shall ensure the presence of a empowered representative of such specific group during all deliberations, if required and possible.

21. Policy to monitor and prevent the conflict of interest

I).Every member of IEC shall sign the Conflict of Interest Agreement Form(annexure-13) before participating in the review process.
ii). The Committee Member with conflicting interest should not accept the protocol for review. The same should be communicated to the Member Secretary / Chairperson / Committee.
iii). In case the member has conflict of interest for any protocol received for review, the member shall immediately inform Member Secretary / Chairperson / Committee well in advance of the scheduled meeting and withdraw from the meeting or withdraw from deliberation of that particular protocol. Another suitable member shall be invited to fulfil the quorum requirements.
iv). If Committee members need information on the study from the member with a conflicting interest, then the member may remain present in the meeting room during presentation of the study. The member must then leave the meeting room during the deliberative discussion and voting of protocol.
v). The same will be recorded in the declaration of Conflict of Interest Form and Minutes of Meeting.

22. Decisions Making

i). All the decisions will be made only in meetings ,where quorum is complete, after adequate discussions and arriving at common consensus.

ii). A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.

iii). Only members will make the decision. The expert or observer can only offer their opinion.

iv). The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.

v). Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

vi).Revised proposals may be subjected to an expedited review.

vii). All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.

a. PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
b. The final report of the completed study should be submitted by PI.
c. The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.
d. PI must submit the progress report of the study every 3 months and must inform the SAEs/AEs immediately to IEC , if any.

Viii). In case where issues remain unresolved in IEC, the researcher can appeal to principal, GDC, Raipur (as the Principal is appellant authority) within 4 weeks of decision communicated . The appeal is directed to member secretary and shall be taken up in next IEC meeting.

23. Communicating the Decision

i). Decision will be communicated to PI by the Member Secretary in writing within 7 working days of meeting convened at which decision was taken . The decision of approval will be sent to PI within 10 days of approval in a specified format.(Annexure-14)

ii). In case of member secretary as PI, the decision of the IEC and other routine correspondence shall be signed/ countersigned by Chairperson of the IEC or a member designated for this purpose by the IEC.

iii). Suggestions for modifications ,if any, and reasons for rejection shall be communicated to the PI.

iv).The schedule / plan of ongoing review by the IEC will be communicated to the Principal Investigator.

v). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

24. Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/ Device/ Collaborative Trials

i). After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Dean, GDC, Raipur with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost.

ii).The drug trial shall be started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

25. Follow up Procedures

i). Progress report should be submitted by the PI at specified interval in prescribed format (Annexure- 15) along with comments to office of the IEC

ii). Final report should be submitted to the IEC at the end of study on prescribed format(Annexure-16) including a copy of the report which has been sent to sponsoring agency.

iii). All SAEs and the interventions undertaken should be intimated immediately to IEC in stipulated proforma (annexure-17 and annexure- 18). The PI should submit the SAEs reported by other centres from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study. Following events are considered as SAEs -

a. The death of a study subject, whether or not related to an investigational agent.
b. A life-threatening adverse event.
c. In patient hospitalization or prolongation of existing hospitalization for more than 24hours (excluding elective hospitalization for conditions unrelated to the study).
d. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life function.
e. A birth defect in an offspring of a study participant, regardless of the time after the study, the congenital defects is diagnosed.

iv). Protocol deviation, if any, should be informed with adequate justifications in specified format(Annexure -19)

v). Any amendment to the protocol should be submitted for approval in prescribed format (Annexure-20)

vi). Any new information related to the study should be communicated to IEC.

vii). Premature termination of study should be notified with reasons along with summary of the data obtained so far (Annexure- 21).

viii). Change of investigators should be done with the approval of IEC.

26. Record Keeping and Archiving

i) Following documents will be properly dated, filed, labelled and archived in secure place in IEC, GDC, Raipur office for future reference-

a. Constitution and composition of IEC, GDC, Raipur
b. Standard Operating Procedures of IEC, GDC, Raipur
c. Updated Curriculum Vitae (CV) of all members of IEC, GDC, Raipur.
d. Minutes of all meetings duly signed by the Chairperson.
e. Copy of all correspondence with members, researchers and other regulatory bodies.
f. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
g. Record of all notification issued for premature termination of a study with a summary of the reasons
h. Final report of the approved projects.
i. Record of all income and expenses of the IEC, including allowances and reimbursements made to the secretariat and EC members.
j. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of 5 years after the completion of study

ii) One soft and hard copy of research protocol will be archived and rest other copies are destroyed after completion of one year

iii) Only authorized person will have access to data related to IEC, GDC, Raipur

27. Policy for updating/training of IEC members:

i) All individual selected as a new member of the IEC will be required to undergo Good clinical practice (GCP) training initially.

ii) All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) annually.

iii) All training including GCP, SOP, New Regulatory guidelines / updates will be conducted by the IEC,GDC, Raipur.

iv) All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.

v) The Chairman, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs/ conferences/ workshops/seminars/courses at least once in a year in the field of research ethics (over and above his own discipline) to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.

vi) IEC Secretariat will maintain the record of training in the minutes. IEC Secretariat will provide the feedback form to the members for any suggestions.

vii) The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

viii) For drug trial review, it is preferable to train the IEC members in Good Clinical Practice

23/12/2022

23/12/22

28. References :

1. WHO Operational guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000). Available at http://whqlibdoc.who.int

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) (2016). Available at https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

3. ICMR Ethical Guidelines for Biomedical Research on Human participants, ICMR (2017/2018). Available at https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf

4. Scheduled Y (The Drugs and Cosmetics Rules, 1945 (As amended up to the 31st December, 2016). Available at https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

5. Common forms for EC review of National Ethics Committee Registry for Biomedical and Health Research , Department of Health Research Ministry of Health and Family Welfare, Government of India. https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/downloads/CommonForms_Ethics_Committee_review.pdf

(Annexure -1)

Constitution of Institutional Ethics Committee of GDC, Raipur

Letter Ref. No. date:

From

Principal
GDC, Raipur

To

.....

.....

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

Dear Sir / Madam,

On behalf of Government Dental College, Raipur, Chhattisgarh, I request your consent for appointment as a Chairperson/Member of Institutional Ethics Committee of GDC, Raipur.

Kindly send your written acceptance in the enclosed format. You are also requested to provide your brief curriculum vitae. On receipt of your acceptance, I shall send you the formal appointment letter.

Thanking you

Yours sincerely,

Name and Signature of Principal , GDC, Raipur

(Annexure _ 2)

Acceptance regarding appointment as Chairperson/Member of IEC- GDC Raipur

From,

.....
.....
.....

To
The Principal
Government Dental College, Raipur

Sub: Acceptance of appointment as Chairperson/Member of Institutional 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 Chairperson/Member of Institutional Ethics Committee (IEC) of GDC, Raipur. 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 am herewith enclosing my curriculum vitae.

Thanking you,

Yours sincerely,

Signature with date

Name of the Chairperson/Member Address:

Office:

Residence:

Tel. NO. -
Mobile: Email:

(Annexure-3)

Appointment order for Chairperson/Member of IEC-GDC Raipur

Letter Ref. No. Date:

To

Respected/ Dear

I am pleased to appoint you as Chairperson/member of the Institutional Ethics Committee (Human Studies)Government Dental College,. Raipur (Chhattisgarh) w.e.f. for a term of year I months provided following conditions of appointment are met.

I) You should be willing to publicize your full name, profession and affiliation.

ii) You are willing to record all reimbursement for work and expenses, if any, within or related to an Ethics Committee and make it available to the public upon request.

iii)You consent to sign confidentiality agreement between you and the IEC- GDC Raipur regarding meeting deliberations, applications, information on research participants, and related matters.

The renewal of your appointment will be by consensus and one month notice on either side will be necessary prior to resignation/ termination of appointment. Terms and conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the SOPs of IEC- GDC, Raipur.

We sincerely hope your association with IEC-GDC Raipur will be fruitful to the College and the Community we serve,

Thanking You.

Yours Sincerely

Name and Signature of Principal
GDC, Raipur

(Annexure -4)

Proforma for Confidentiality Agreement

IEC-GDC, Raipur

In recognition of the fact, that I ----------

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC, have been given responsibility to assess research studies involving human participants in order to ensure that they are conducted in a human and ethical manner, adhering to GCP guidelines, national and international guidelines and highest standards of care as per the national, and local regulations and institutional policies.

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols and make a determination and the best possible objective recommendations without bias.

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well- being of research participants; The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, ...(name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature Date

(Annexure-5)

Application Form for Initial Review

Government Dental College, Raipur (C.G.)

IEC Ref. No. (For office use):

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable

SECTION -A BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

a. Name of Organization
b. Name of Ethics Committee:
c. Name of Principal Investigator:
d. Department/Division:
e. Date of submission:
f. Type of review requested: Exemption from review / Expedited review / Full committee review
g. Title of the study:

h. Protocol number (If any): Version number:
i. Details of Investigators;

Name	Designation and Qualification	Department and Institution	Address for communication
Principal Investigator/Guide			
Co-investigator/student/fellow			

j. Number of studies where applicant is a:
   i. Principal Investigator at time of submission:
   ii. Co-Investigator at time of submission:
k. Duration of the study:

2. FUNDING DETAILS AND BUDGET

a. Total estimated budget for site:
   At site In India Globally
b. Self-funding Institutional funding Funding agency *(Specify)*

SECTION -B, RESEARCH DETAILED INFORMATION

1. OVERVIEW OF RESEARCH

A. Lay summary (within 300 words):

B. Type of study:

i. Basic Sciences
ii. Clinical
iii. Cross Sectional
iv. Retrospective
v. Prospective
vi. Qualitative
vii. Quantitative
viii. Mixed Method
ix. Epidemiological/ Public Health
x. Socio-behavioural
xi. Biological samples/ Data
xii. Case Control
xiii. Cohort
xiv. Systematic Review
xv. Any others *(Specify)*

C. METHODOLOGY

a. Sample size/ number of participants (as applicable)

At site..... In India..... Globally.....

Control group..... ..... Study group .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for Saturation.....

b. Is there an external laboratory/outsourcing involved for investigations? Yes / No / NA

c. How was the scientific quality of the study assessed?

i. Independent external review
ii. Review by sponsor/Funder
iii. Review within PI's institution
iv. Review within multi-centre research group
v. No review

d. Date of review:

e. Comments of scientific committee, if any (100 words)

SECTION C: PARTICIPANT RELATED INFORMATION

1. RESEARCH PARTICIPANTS IN STUDY
   - **a.** Healthy volunteers
   - **b.** Patients
   - **c.** Vulnerable persons/ Special groups
   - **d.** Others *(Specify)*
2. PARTICIPANTS RECRUITMENT

I. Who will do the recruitment?

II. Participant recruitment methods used:
   a. Posters/ leaflets/Letters
   b. TV/Radio ads / Social media / Institution website
   c. Patients / Family / Friends
   d. Visiting hospitals
   e. Telephone
   f. Others(specify)

III. A. Will there be vulnerable persons / special groups involved? Yes / No / NA

If yes, type of vulnerable persons / special groups
   a. Children under 18yrs
   b. Pregnant or lactating women
   c. Differently abled (Mental/Physical)
   d. Elderly
   e. Economically and socially disadvantaged
   f. Terminally ill (stigmatized or rare diseases)
   g. Employees/Students/Nurses/Staff
   h. Institutionalized
   i. Refugees/Migrants/Homeless
   j. Any other *(Specify)*:

B. Provide justification for inclusion/exclusion

C. Are there any additional safeguards to protect research participants?

3. Is there any reimbursement to the participants? Yes / No
   If yes, i. Monetary ii. Non-monetary
   Provide details:

4. Are there any incentives to the participants? Yes / No
   If yes, i. Monetary ii. Non-monetary
   Provide details:

5. Are there any participant recruitment fees/ incentives for the study provided to the PI institution?

If yes, Provide details i. Monetary ii. Non-monetary

6. BENEFITS AND RISK

I. i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes /No

If yes, categorize the level of risk

a. Less than Minimal risk
b. Minimal risk
c. Minor increase over minimal risk or low risk
d. More than minimal risk or high risk

ii. Describe the risk management strategy:

II. What are the potential benefits from the study?

a. For the participant
   i. Direct ii. Indirect
b. For the society/community
   i. Direct ii. Indirect
c. For improvement in science
   i. Direct ii. Indirect.

Please describe how the benefits justify the risks:

III. Are adverse events expected in the study Yes / No / NA

IV. Are reporting procedures and management strategies described in the study Yes / No

If Yes, Specify:

7. INFORMED CONSENT

I). Are you seeking waiver of consent? Yes / No

If yes, please specify reasons

II). a. Version number and date of Participant Information Sheet (PIS):
b. Version number and date of Informed Consent Form (ICF):

III). Type of consent planned for:

a. Signed consent
b. Verbal/Oral consent
c. Witnessed consent
d. Audio-Video (AV) consent
e. Consent from LAR(If so, specify from whom)
f. For children<7yrs -parental/LAR consent
g. Verbal assent from minor (7-12 yrs) along with parental consent
h. Written assent from minor (13-18 yrs) along with parental consent
i. Other (specify):

IV). Who will obtain the informed consent?

a. PI/Co-I
b. Nurse/Counsellor
c. Research Staff
d. Other *(Specify)*

Any tools to be used:

V). Participant Information Sheet (PIS) and Informed Consent Form (ICF)

a. English
b. Local language
c. Other *(Specify)*

List the languages in which translations were done:
If translation has not been done, please justify:

VI). Provide details of consent requirements for previously stored samples if used in the study

VII). Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

a. Simple language
b. Data/ Sample sharing
c. Compensation for study related injury
d. Risks and discomforts
e. Alternatives to participation
f. Right to withdraw
g. Benefits
h. Purpose and procedure
i. Need to recontact
j. Confidentiality
k. Storage of samples
l. Return of research results
m. Payment for participation
n. Statement that consent is voluntary
o. Commercialization/ Benefit sharing
p. Statement that study involves research
q. Use of photographs/ Identifying data
r. Contact information of PI and Member Secretary of IEC
s. Others (Specify):

8. PAYMENT/COMPENSATION

I. Who will bear the costs related to participation and procedures?
   a. PI
   b. Institution
   c. Sponsor
   d. Other agencies*(specify)*

II. Is there a provision for free treatment of research related injuries? Yes / No / NA
If yes, then who will provide the treatment

III. Is there a provision for compensation of research related SAE Yes / No / NA
If yes, specify:

IV. Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes / No / NA
If yes, specify.

V. Is there a provision for ancillary care for unrelated illness during the study period? Yes / No/ NA
If yes, please specify

9. STORAGE AND CONFIDENTIALITY

a. Identifying Information: Study Involves samples/data Yes /No. /NA
If Yes, specify

i. Anonymous/Unidentified
ii. Anonymized: Reversibly coded
ii. Irreversibly coded
iii. Identifiable
iv. If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

b. Who will be maintaining the data pertaining to the study?

c. Where will the data be analyzed and by whom?

d. For how long will the data be stored?

e. Do you propose to use stored samples/data in future studies? Yes / No / Maybe
If yes, explain how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

1. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a. Will the results of the study be reported and disseminated? If yes, specify. Yes / No / NA

b. Will you inform participants about the results of the study? Yes / No / NA

c. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes / No / NA

If yes describe in brief (Max 50 words)

d. Is there any plan for post research benefit sharing with participants? Yes /No /NA
If yes, specify

e. Is there any commercial value or a plan to patent/IPR issues? Yes /No /NA
If yes, please provide details

f. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes / No
If yes, provide details.

SECTION E: DECLARATION

DECLARATION (Please tick as applicable)	
I/We certify that the information provided in this application is complete and correct.	
I/We confirm that all investigators have approved the submitted version of proposal/related documents.	
I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.	
I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.	
I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.	
I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.	
I/We declare that the expenditure in case of injury related to the study will be taken care of.	
I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.	
I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.	
I/We confirm that we will maintain accurate and complete records of all aspects of the study.	
I/We will protect the privacy of participants and assure confidentiality of data and biological samples.	
I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.	
I/We have the following conflict of interest (PI/Co-I): 1. .... 2.	
I/We declare/confirm that all necessary government approvals will be obtained as per requirements where ever applicable	

Name of PI: .....

Signature: .....

Name of Co-PI: .....

Signature: .....

Name of Guide: .....

Signature: .....

Name of HOD: .....

Signature: .....

SECTION F: CHECKLIST

A. ADMINISTRATIVE AND PROPOSAL REATED REQUIREMENTS

a. Mandatory for all protocol

1. Cover letter
2. Brief CV of all Investigators
3. Approval of scientific committee
4. Copy of the detailed protocol
5. Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated in local language)
6. Duly filled application form for initial review

b. if applicable

7. IEC clearance of other centers, in case of collaborative research
8. Agreement between collaborating partners, in case of collaborative research
9. MTA between collaborating partners, in case of collaborative research
10. Good Clinical Practice (GCP) training of investigators in last 3 years
11. Insurance policy/certificate
12. Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification
13. Copy of contract or agreement signed with the sponsor or donor agency
14. Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other IECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol
15. Investigators Brochure (If applicable for drug/biologicals/device trials)
16. Assent form for minors (12-18 years) (English and Translated)
17. Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)
18. Advertisement/material to recruit participants (fliers, posters etc)

B. PERMISSION FROM GOVERNING AUTHORITIES, IF APPLICABLE

1. CTRI (Clinical Trial Registry-India)
2. DCGI (Drug Controller General of India)
3. HMSC (Health Ministry Screening Committee)
4. NAC-SCR (National Apex Committee for Stem Cell Research and Therapy)
5. ICSCR (Institutional Committee for Stem Cell Research)
6. RCGM (Review Committee for Genetic Manipulation)
7. GEAC (Genetic Engineering Approval Committee)
8. BARC (Bhabha Atomic Research Centre)
9. Tribal Board
10. Others (Specify)

(Annexure-06)

Format for Curriculum Vitae for Investigators

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

1. **Name**
2. **Present affiliation** ***(Job title, department, and organisation)*****:**
3. **Address (Full work address):**
4. **Telephone number/ Mob. No.-** **Email address:**
5. **Qualifications:**
6. **Professional registration (Name of body, registration number and date):**
7. **Previous and other affiliations (Include previous affiliations in the last 5 years and other current affiliations):**
8. **Projects undertaken in the last 5 years:**
9. **Relevant research training/experience in the area :**
10. **Relevant publications** ***(Give references to all relevant publications in the last five years):***

Signature and name with date

(Annexure-07)

Application Form for Exemption from Review

Government Dental College, Raipur (C.G.)

Title of study:

IEC Ref. No. *(For office use):*

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why exemption from ethics review is requested?

   i. Research on data in the public domain/ systematic reviews or meta-analyses
   ii. Observation of public behavior / information recorded without linked identifiers and disclosure would not harm the interests of the observed person
   iii. Quality control and quality assurance audits in the institution
   iv. Comparison among instructional techniques, curricula, or classroom management methods
   v. Consumer acceptance studies related to taste and food quality
   vi. Public health programmes by government agencies
   vii. Any other (please specify in 100 words):

Signature of PI: Date

Comments of EC Secretariat:

Signature of Member Secretary: Date

(Annexure-8)

Application Form for Expedited Review

Government Dental College, Raipur (C.G.)

IEC Ref. No. (For office use)

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested?
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records).
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)).
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal.
   v. Minor deviation from originally approved research causing no risk or minimal risk.
   vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis.
   vii. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.
   viii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre.
   ix. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017)
   x. Any other (please specify)

2. Is waiver of consent being requested? Yes / No
3. Does the research involve vulnerable persons? Yes / No

If Yes, give details

Signature of PI: Date

Comments of EC Secretariat:

Signature of Member Secretary:

(Annexure-09)

Application Form for Clinical Trials

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study

Principal Investigator (Name, Designation and Affiliation):

1. **Type of clinical trial** **i. Regulatory trial** **ii. Academic trial**

   CTRI registration number: NABH accreditation number: EC registration number:
2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached: Applied, under process:

   Not applied (State reason):
3. Tick all categories that apply to your trial
   a. Phase - I
   b. Phase II
   c. Phase III
   d. Phase IV or Post Marketing Surveillance
   e. Investigational medicinal products
   f. Investigational New drug
   g. New innovative procedure
   h. Medical devices
   i. Drug/device combination
   j. Bioavailability/Bioequivalence studies
   k. Non-drug intervention
   l. Repurposing an existing intervention
   m. Indian system of medicine (AYUSH)
   n. Stem cells
   o. Phytopharmaceutical drug
   p. Approved drug for any new indication or new route ofadministration
   q. Others (specify)
4. Trial design of the study-

   I. Types
   a. Randomized
   b. Non randomized
   c. Parallel
   d. Cross-over
   e. Cluster
   f. Matched-pair
   g. Factorial
   h. Stratified
   i. Adaptive

j. Comparison trial
k. Superiority trial
l. Non-inferiority trial
m. Equivalence trial
n. Others (specify)

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

III. Describe the method of allocation concealment (blinding / masking), if applicable.

5. List the primary / secondary outcomes of the trial.

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes /No
If yes, Name and Contact details:

7. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)
a. Regulatory affairs
b. Data management
c. Statistical support
d. Medical writing
e. Site management
f. Audits, quality control, quality assurance
g. Finance management
h. Recruitment and training
i. Administrative support
j. Others (specify):

8. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; Yes / No / NA
if yes, provide regulatory approval details.

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details
Yes / No / NA

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

IV. Provide details of patent of the drug/s, device/s and biologics

9. Describe in brief any preparatory work or site preparedness for the protocol? Yes / No / NA
If yes, provide details (100words)

10. Is there an initial screening/ use of existing database for participant selection? Yes / No / NA
If yes, provide details of arrangements made to address them.

11. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention? Yes / No / NA
If yes, provide details of arrangements made to address them.

12. Does the study use a placebo? Yes / No / NA
If yes, justify the use of the placebo and risks entailed to participants.

13. Does the study use a placebo? Yes / No / NA
If yes, justify the use of the placebo and risks entailed to participants

14. Are there any plans to withdraw standard therapy during the study? Yes / No / NA
If yes, please justify

15. Are there any rules to stop the protocol in case of any adverse events? Yes / No / NA
If yes, please specify

16. Does the study have a Data and Safety Monitoring Plan? Yes / No / NA
If no, please justify.

17. Participant Information Sheet(PIS) and Informed Consent Form (ICF)
English / local language/ other
List the languages in which translations were done
Justify if translation not done

18. Involvement/consultation of statistician in the study design Yes/ No/ NA

19. Is there any insurance coverage of the trial? Yes/ No/ NA
If yes, provide details.

20. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?
Please provide details.

21. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate

Signature of PI Date

(Annexure- 10)

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital or other facility where the research will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained. I inform that no work has been started for this research yet.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s)in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with date.

Annexure -11

General Format for Participant/Patient/Volunteer Information Sheet

Instructions

Potential participants in research/trial study must be given sufficient information to allow them to decide whether or not they want to take part . The participant information sheet should address the subject of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. While formulating this sheet, the investigator must provide the following information in questionnaire form as applicable in a simple language in English and Hindi/Other local language(s) which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study o Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigator

Government Dental College & Hospital
Raipur, Chhattisgarh,492001

Participant Information Sheet (PIS)
(for Participants in Research Programs involving studies on human beings)

Study Title----------

Name Of Investigator----------

1. Introduction of the Study

2. what is the purpose of the study?

3. Why have I been chosen?

4. Do I have to take part?

5. How long will the study last?

6. What do I have to do?

7. What is the drug or procedure that is being tested?

8. What are the alternatives for diagnosis or treatment?

9. What are the side effects of taking part?

10. What are the possible disadvantages and risks of taking part?

11. What are the benefits of the study ?

12. What happens, if new information becomes available ?

13. What happens when the study stops ?

14. What if something goes wrong ?

15. Will my taking part be kept confidential ?

16. What else should I know ?

17. Who is organizing and funding the research/trial?

18. Who has reviewed the study?

19. Whom to call with questions ?

Signature of Participant:----------Date----------
Signature of Principal Investigator----------Date----------

शासकीय दंत चिकित्सा महाविद्यालय, एवं चिकित्सालय
रायपुर (छ.ग.–492001)

प्रतिभागी सुचना पत्र
(मानव सम्मिलित अनुसंधान कार्यकमो मे शामिल प्रतिभागियो हेतु)

अध्ययन का शीर्षक .....

.....

शोध अध्ययन की प्रस्तावना

1. अध्ययन का उद्देश्य क्या है ?
2. मुझे क्यों चुना गया है ?
3. क्या मुझे भाग लेना है ?
4. अध्ययन कितने समय तक चलेगा ?
5. अगर मैं भाग लेता हूं तो मेरा क्या होगा ?
6. मुझे क्या करना है ?
7. किस दवा अथवा विधि का परीक्षण किया जा रहा है ?
8. ईलाज अथवा निदान का विकल्प क्या है ?
9. अध्ययन में भाग लेने से प्रतिकूल प्रभाव क्या हो सकते है?

10. अध्ययन में भागीदारी के संभावित हानि एवं जोखिम क्या है?

11. अध्ययन के क्या लाभ हैं ?

12. क्या होगा अगर नई जानकारी उपलब्ध हो जाती है ?

13. क्या होगा अगर अध्ययन रूक जाता है ?

14. अगर कुछ गलत हो जाए तो क्या होगा ?

15. क्या मेरा हिस्सा लेना गोपनीय रखा जाएगा ?

16. मुझे और क्या पता होना चाहिए ?

17. शोध/परीक्षण कौन आयोजित एवं वित्तपोषण करेगा?

18. अध्ययन की समीक्षा किसने की है?

19. प्रश्न पुछने के लिए किससे सम्पर्क करना है ?

प्रतिभागी का हस्ताक्षर ..... दिनांक

अन्वेषक का हस्ताक्षरः..... दिनांक

Annexure-12 (Form-A)

Government Dental College & Hospital
Raipur, Chhattisgarh,492001

Informed Consent Form (ICF)
(for Participants more than 18 years of age in Research Programs involving studies on human beings)

STUDY TITLE: ----------

Study Number: ----------

Subject's Name: ----------
Date of birth: ----------Age: . ----------

Address of the Subject ----------

Qualification. ---------- Annual Income of Subject----------

Occupation: Self-Employed Service/ House-wife/Others: (Please tick as appropriate)

Details of Nominee(S) :

Name of Nominee ----------

Address of Nominee: ----------

Relation to Subject: ----------

1. I confirm that I have read and understood the information sheet dated--------- for the above study and have had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the Current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I agree to take part in the above study.

Signature of the Participants:_____

(Or Thumb impression)

Date:----------

Study Participant's Name:----------

Signature of the Principal Investigator----------

Date:----------

Principal Investigator/ Study Researcher Name:----------

Signature of the witness:----------

Date:----------

Name of the witness----------

शासकीय दंत चिकित्सा महाविद्यालय, एवं चिकित्सालय

रायपुर (छ.ग.–492001)

सूचित सहमति पत्र

(मानव सम्मिलित अनुसंधान कार्यकमो मे शामिल 18 वर्ष से अधिक आयु वाले प्रतिभागियो हेतु)

अध्ययन का शीर्षक .....

.....

अध्ययन संख्या .....

प्रतिभागी का नाम .....

जन्म तिथि .....आयु.....

प्रतिंभागी का पता .....

.....

प्रतिभागी योग्यताः .....प्रतिभागी की वार्षिक आय.....

प्रतिभागी का व्यवसाय स्व – नियोजित / सेवा/ हाउस वाइफ/ अन्य .....

नामांकित व्यक्ति का विवरणः–

नामांकित व्यक्ति का नाम .....

नामांकित व्यक्ति का पता .....

प्रतिभागी से संबंध .....

1 मैं इस बात की पुष्टि करता/करती हूं कि उपयुर्क्त अध्धययन हेतु दिनांक.....के सूचना पत्र को मैंने पढ़ी और समझी, और उपरोक्त अध्ययन हेतु प्रश्न पूछने का मुझे पर्याप्त अवसर मिला है । मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी समय, बिना किसी कारण बताए, मेरी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए वगैर, अपना भागीदारी वापस लेने के लिए स्वतंत्र हूँ ।

2 मैं समझता हूं कि नैदानिक परीक्षण के प्रायोजक, प्रायोजक की ओर से अधिकृत व्यक्ति, नैतिकता समिति और इससे संबंधित नियामक अधिकारियों को मेरे स्वास्थ्य रिकॉर्ड, जो वर्तमान अध्ययन अथवा इससे संबंधित अन्य किसी शोध से संबंध रखता हो, को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण से अपना भागीदारी वापस लेता हूं । मैं इसके लिए सहमत हूं । यद्यपि , मैं जानता हूँ कि मेरी पहचान तीसरे पक्ष को जारी किसी भी सूचना या प्रकाशन मे उद्धृत नहीं की जाएगी ।

3 मै इस अध्ययन से प्राप्त किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं , बशर्ते उसका उपयोग केवल वैज्ञानिक उद्देश्य (ओं) के लिए हो ।

4 मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं ।

प्रतिभागी का हस्ताक्षर .....
(या अंगूठे का निशान)
दिनांक .....
अध्ययन प्रतिभागी का नाम .....

मुख्य अन्वेषक का हस्ताक्षर .....
दिनांक .....
मुख्यअन्वेषक /अध्ययनकर्ता का नाम.....

गवाह का हस्ताक्षरः.....
दिनांक.....
गवाह का नाम.....

Annexure-12 (Form-B)

Government Dental College & Hospital
Raipur, Chhattisgarh,492001

Informed Consent Form (ICF)
(for Participants less than 18 years of age in Research Programs involving studies on human beings)

STUDY TITLE: ----------

Study Number: ----------

Subject's Name: ----------
Date of birth: ----------Age: . ----------

Address of the Subject ----------

Occupation: Self-Employed Service/ House-wife/Others: (Please tick as appropriate)

Details of Parent/LAR's (Legally Authorised Representative) Name:

Name of **Parent/LAR's:** ----------

Address of **Parent/LAR's:** ----------

Relation to Subject: ----------

1. I confirm that I have read and understood the information sheet dated--------- for the above study and have had the opportunity to ask questions.

2. I understand that participation of my child/ward in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without medical care or legal rights of my child being affected.

3. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my child health records both in respect of the Current study and any further research that may be conducted in relation to it, even if I withdraw my child / ward from the trial. I agree to this access. However, I understand that my child identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I fully agree for participation of my Child/ward in the above study.

Signature of the **Parent/LAR's**:_____

(Or Thumb impression)

Date:----------

Name of **Parent/LAR's**:----------

Signature of the Principal Investigator----------

Date:----------

Principal Investigator/ Study Researcher Name:----------

Signature of the witness:----------

Date:----------

Name of the witness----------

अनुलग्नक–12 परिपत्र (ब)

शासकीय दंत चिकित्सा महाविद्यालय, एवं चिकित्सालय

रायपुर (छ.ग.–492001)

सूचित सहमति पत्र

(मानव सम्मिलित अनुसंधान कार्यक्रमो मे शामिल 18 वर्ष से कम आयु वाले प्रतिभागियो हेतु)

अध्ययन का शीर्षक .....

.....

अध्ययन संख्या .....

प्रतिभागी का नाम .....

जन्म तिथि .....आयु.....

प्रतिभागी का पता .....

.....

प्रतिभागी योग्यताः .....प्रतिभागी की वार्षिक आय.....

प्रतिभागी का व्यवसाय स्व – नियोजित / सेवा/ हाउस वाइफ/ अन्य .....

माता–पिता/वैधानिक प्रतिनिधि का विवरणः–

माता–पिता/वैधानिक प्रतिनिधि का नाम .....

माता–पिता/वैधानिक प्रतिनिधि का पता .....

प्रतिभागी से संबंध .....

1 मैं इस बात की पुष्टि करता/करती हूं कि उपयुर्क्त अध्धययन हेतु दिनांक.....के सूचना पत्र को मैंने पढ़ी और समझी, और उपरोक्त अध्ययन हेतु प्रश्न पूछने का मुझे पर्याप्त अवसर मिला है ।

2 मैं समझता हूं कि अध्ययन में मेरे संतान/संरक्षित बालक/बालिका की भागीदारी स्वैच्छिक है और मै किसी भी समय, बिना किसी कारण बताए, मेरे संतान/संरक्षित बालक/बालिका की चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए वगैर, उसकी भागीदारी वापस लेने के लिए स्वतंत्र हूँ ।

3 मैं समझता हूं कि नैदानिक परीक्षण के प्रायोजक, प्रायोजक की ओर से अधिकृत व्यक्ति, नैतिकता समिति और इससे संबंधित नियामक अधिकारियों को मेरे संतान/संरक्षित बालक/बालिका का

स्वास्थ्य रिकॉर्ड, जो वर्तमान अध्ययन अथवा इससे संबंधित अन्य किसी शोध से संबंध रखता हो, को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण से उसकी भागीदारी वापस लेता हूं । मैं इसके लिए सहमत हूं । यद्यपि , मैं जानता हूँ कि मेरे संतान/संरक्षित बालक/बालिका की पहचान तीसरे पक्ष को जारी किसी भी सूचना या प्रकाशन मे उद्धृत नहीं की जाएगी ।

4 मै इस अध्ययन से प्राप्त किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं , बशर्ते उसका उपयोग केवल वैज्ञानिक उद्देश्य (ओं) के लिए हो ।

5 मैं उपरोक्त अध्ययन में मेरे संतान/संरक्षित बालक/बालिका की भागीदारी के लिए सहमत हूं ।

माता–पिता/वैधानिक प्रतिनिधि का हस्ताक्षर .....
(या अंगूठे का निशान)
दिनांक .....
अध्ययन प्रतिभागी के **माता–पिता/वैधानिक प्रतिनिधि** का नाम .....

मुख्य अन्वेषक का हस्ताक्षर .....
दिनांक .....
मुख्यअन्वेषक /अध्ययनकर्ता का नाम.....

गवाह का हस्ताक्षरः.....
दिनांक.....
गवाह का नाम.....

Annexure 12 (Form -C)

Government Dental College & Hospital
Raipur, Chhattisgarh,492001

Assent Form for participants of age 12-18 years

Name of Principal Investigator:
Name of Participant(child):

Title:

1. We are doing a research study. I am .....(investigator or his representative's name)
2. We are doing this study to find out..... (the purpose of your study)
3. We are asking you to take part in this study because you .....(give reason)
4. We will only take you if you allow us. If you do not want to do so your treatment will continue as usual. If you decide to take part now, but wish to discontinue later, you can tell us and we will take you out of the study.
5. Once you agree to take part, you will have to..... (mention procedures that will be done)
6. These procedures can..... (write about risks/discomforts)
7. It is possible that the study will help you feel better. It can also occur that you do not get any benefit but the information we get from you may help other children in future.
8. We have asked your parents [or guardian] for their permission and it is all right with them.
9. Do not hesitate to ask questions. You can also ask us about anything later on if there are no questions right now.

Assent of Child

I have been explained about the study and I agree to take part in it.

Participant's signature/Thumb Impression:

Certificate of investigator or his/her representative for obtaining assent

The child can read the assent form and was able to understand it

The child was not capable of reading the assent form. but I verbally explained the information.

Signature of investigator or his/her representative:
Date:
Name of investigator or his/her representative

Annexure 12 (Form -D)

Government Dental College & Hospital
Raipur, Chhattisgarh,492001

Assent form for children ages from birth to 6 years of age

Signature page for research involving children ages from birth to 6 years of age or unable to provide assent for other reasons Parents/Legally accepted representative (LAR)

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study.
3. I have been given a full explanation of the procedures involved.
4. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
5. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
6. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
7. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
8. I have been explained the risks and benefits for the patients and society associated with the study.
9. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
10. I agree that the biological samples collected during this study may be stored for future use I willingly agree that my child will take part in the above study.

Signature of the parent/guardian
Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator:
Date:

Signature of the witness:
Date:

(Annexure-13)

Conflict of Interest Agreement Form for IEC Members

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.
When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC.
A copy will be given to you for your records.
Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.
I, ...(name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature Date

Annexure=14(A)

GOVERNMENT DENTAL COLLEGE RAIPUR (C.G.)

Institutional Ethics Committee (Human Studies)

No.IEC: ECR/ /GDC/CG/2022 **Date:** / /2022

IEC APPROVAL NOTICE

To:

Re: IEC Proposal No. ----------Dated

[TITLE OF STUDY – ----------

I am pleased to inform you that the IEC voted to approve the referenced protocol from ethical review in the meeting convened for the consideration of protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and addenda to the protocol must be submitted to the IEC for review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
3. Adverse events should be reported to the IEC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. 1he IRB may conduct audits ot all study records, and consent documentation may be part of such audits
5. GDC Raipur lEC Office require progress review of an approved study not less than once per 3month period. **Therefore, a continuing progress review application must be submitted to the lEC in order to continue the study beyond the approved period**. Failure to submit a continuing progress review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
6. The proposal must be registered in Clinical Trial Registry- India (CTRI) within a month or before recruitment of first subject in the study

Sincerely,

Member Secretary, Ethics Committee
Govt. Dental College, Raipur

Chairperson, Ethics Committee
Govt. Dental College, Raipur

Annexure=14(B)

GOVERNMENT DENTAL COLLEGE RAIPUR (C.G.)

Institutional Ethics Committee (Human Studies)

No.IEC: ---------- **Date: ----------**

IEC EXEMPTION NOTICE

To:

Re: IEC Proposal No . ----------

[TITLE OF STUDY – ----------

I am pleased to inform you that the IEC voted to exempt the referenced protocol from ethical review in the meeting convened for the consideration of protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and addenda to the protocol must be submitted to the IEC for review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
3. If any bio-waste, involved / produced during this in- vitro study, must be disposed of as per bio-waste disposal protocols.
4. Any adverse events/objections should be reported to the IEC. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.

Sincerely,

Member Secretary, Ethics Committee
Govt. Dental College, Raipur

Chairperson, Ethics Committee
Govt. Dental College, Raipur

(Annexure-15)

Continuing Review / Annual report format

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval:
2. Validity of approval:
3. Date of Start of study:
4. Date of completion of study:
5. Period of Continuing Report : -------To -----
6. Does the study involve recruitment: - Yes / No

(a) If yes, Total number expected Number Screened: Number Enrolled:

Number Completed: Number on follow up:

(b) Enrolment status – ongoing / completed/ stopped

(c) Report of DSMB- Yes / No / NA

(d) Any other remark

7. Have any participants withdrawn from this study since the last approval? - Yes / No / NA

If yes, total number withdrawn and reasons:

8. Is the study likely to extend beyond the stated period? Yes / No

If yes, please provide reasons for the extension.

9. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?
If No, skip to item no. 9. Yes / No

   a. If yes, date of approval for protocol and ICD:
   b. In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes / No

   If yes, when / how:

10. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes / No

If yes, discuss in detail:

11. Have any ethical concerns occurred during this period? Yes / No

If yes, give details

12. (a) Have any adverse events been noted since the last review? Yes / No

Describe in brief:

(b) Have any SAE's occurred since last review? Yes / No

If yes, number of SAE's :

Type of SAE's:

(c)Is the SAE related to the study? Yes / No

Have you reported the SAE to EC? Yes / No

If no, state reasons

13. Has there been any protocol deviations/violations that occurred during this period? Yes / No

If yes, number of deviations

Have you reported the deviations to EC? Yes / No

If no, state reasons

14.In case of multi-centric trials, have reports of off-site SAEs been submitted to the EC ? Yes / No / NA

15. Are there any publications or presentations during this period? Yes / No

If yes give details

16. Any other comments

Signature of PI: Date

(Annexure-16)

Study completion/Final report format

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval:
2. Date of start of study:
3. Date of study completion
4. Provide details of:
   a. Total number of study participants approved by the EC for recruitment:
   b. Total number of study participants recruited:
   c. Total number of participants withdrawn from the study (if any):
      Provide the reasons for withdrawal of participants--

5. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared

6. Describe the main ethical issues encountered in the study (if any)

7. Number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
   Deviations: Violation: Amendments:

8. Describe in brief plans for archival of records / record retention

9. Is there a plan for post study follow-up? Yes / No

If yes, describe in brief:

10. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes / No

If yes, describe in brief

11. Is there a plan for post study benefit sharing with the study participants? Yes / No

If yes, describe in brief:

12. Describe results (summary) with Conclusion

13. Number of SAEs that occurred in the study:

14. Have all SAEs been intimated to the EC Yes / No

15. Is medical management or compensation for SAE provided to the participants? Yes / No

If yes, provide details:-

Signature of PI: Date

(Annexure-17)

Serious Adverse Event Reporting Format (Biomedical Health Research)

Government Dental College, Raipur (C.G.)

IEC Ref. No. (For office use):

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Participant details :
   a. Initials and ID
   b. Age at the time of event
   c. Gender
   d. Weight: (Kgs)
   e. Height: (cms)
2. Suspected SAE diagnosis:
3. a. Date of onset of SAE:
   b. Date of reporting SAE:
   c. Describe the event:
4. Details of suspected intervention causing SAE
5. Report type: a. Initial b. Follow up. C. Final
   If Follow-up report, state date of Initial report:
6. Have any similar SAE occurred previously in this study? Yes / No
   If yes, please provide details.
7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?
   (Please list number of cases with details if available)
8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)
   A. i)Expected event ii) Unexpected event
   B. i. Hospitalization
      ii. increased Hospital stay
      iii. Death
      iv. Congenital anoma- ly/birth defect
      v. Persistent or significant disability/incapacity
      vi. Event requiring inter- vention (surgical or medical) to prevent SAE
      Vii. Event which poses threat to life
      Viii. Other
      In case of death, state probable cause of death:.....

C. Changes observed:

i. No permanent/significant functional/cosmetic impairment
ii. Permanent/significant functional/cosmetic impairment
iii. Not Applicable

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

11. Outcome of SAE
    a. Fatal
    b. Recovered
    c. Continuing
    d. Recovering
    e. Unknown
    f. Other *(specify)*

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

13. Provide any other relevant information that can facilitate assessment of the case such as medical history

Signature of PI: Date:

(Annexure-18)

Serious Adverse Event Reporting Format (Clinical trials)

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Participant details :

a. Initials and Case No./ ID:
b. Age at the time of event:
c. Gender:
d. Weight:
e. Height:
2. Report type: Initial /Follow-up /Final

If Follow-up report, state date of Initial report-

3. Assessment of relatedness to the trial in the initial report-

a. By PI – Related/ unrelated
b. By Sponsor – Related/ unrelated
c. By EC – Related/ unrelated

4. Describe the event and specify suspected SAE diagnosis-
5. Date of onset of SAE:
6. Date of reporting:
7. Onset lag time after administration of intervention;
8. Location of SAE (Clinic/Ward/Home/Other)

9. Details of suspected study drug/device/investigational procedure causing SAE:

a. Suspect study drug (include generic name) device/intervention-

b. Indication(s) for which suspect study drug was prescribed or tested

c. Route(s) of administration, daily dose and regimen, dosage form and strength

d. Therapy start date:
e. Stop date:

10. Was study intervention discontinued due to event- Yes / No

11. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? - Yes / No

If yes, provide details about the reduced dose-

12. Did the reaction reappear after reintroducing the study drug / procedure? - Yes / No / NA

If yes, provide details about the dose-

13. Concomitant drugs history and lab investigations:
    a. Concomitant drug (s) and date ofadministration:

    b. Relevant test/laboratory data with dates:

    c. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc.-

14. Have any similar SAE occurred previously in this study? If yes, please provide details-

15. Seriousness of the SAE:
    a. Death
    b. Life threatening
    c. Hospitalization-initial or prolonged
    d. Disability
    e. Congenitial anomaly
    f. Required intervention toprevent permanent impairment / damage-
    g. Other *(specify)*-

16. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom

17. Outcome of SAE:
    a. Fatal
    b. Recovering
    c. Recovered
    d. Unknown
    e. Other (specify)

18. Was the research participant continued on the trial? - Yes / No / NA

19. Provide details about PI's final assessment of SAE relatedness to trial

20. Has this information been communicated to sponsor/CRO/regulatory agencies? - Yes / No

Provide details if communicated (including date)-

21. Does this report require any alteration in trial protocol? - Yes / No

22. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom –

Signature of PI:- **Date**

(Annexure-19)

Protocol Violation/Deviation Reporting Form
(Reporting by case)

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval:
2. Date of start of study:
3. Participant ID:
4. Total number of deviations /violations reported till date in the study: Date of occurrence

4. Deviation/Violation identified by:
   a. Principal Investigator / study team b. Sponsor/Monitor c.SAE Sub Committee/IEC
5. Is the deviation related to (Tick the appropriate related reason):

   a. Consenting
   b. Source documentation
   c. Enrollment
   d. Staff
   e. Laboratory assessment
   f. Participant noncompliance
   g. Investigational Product
   h. Safety Reporting
   i. Other (specify)

6 . Provide details of Deviation/Violation:

7. . Corrective action taken by PI/Co-I:

8. Impact on (if any): a. Study participant b. Quality of data
9. Are any changes to the study/protocol required? Yes / No
   If yes, give details

Signature of PI: Date

(Annexure-20)

Application/Notification form for Amendments

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval
2. Date of start of study
3. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD

3. Impact on benefit-risk analysis Yes / No

If yes, describe in brief:

4.Is any reconsent necessary Yes / No

If yes, have necessary changes been made in the informed consent? Yes / No

5.Type of review requested for amendment:

i)Expedited review (No alteration in risk to participants)

ii)Full review by EC (There is an increased alteration in the risk to participants)

6.Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI: Date:

(Annexure-21)

Premature Termination/Suspension/ Discontinuation Report Format

Government Dental College, Raipur (C.G.)

IEC Ref. No. *(For office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval:
2. Date of start of study:
3. Date of last progress report submitted to EC:
4. Date of termination/suspension/discontinuation
5. Tick the appropriate
   - i. Premature Termination
   - ii. Suspension
   - iii. Discontinuation

Reason for Termination/Suspension/Discontinuation:

Action taken post Termination/Suspension/Discontinuation (if any):

6. Plans for post study follow up/withdrawal (if any):

7. Details of study participants:
   - i. Total participants to be recruited:
   - ii. Screened:
   - iii. Screen failures:
   - iv. Enrolled:
   - v. Consent Withdrawn:
     Reason (Give details):
   - vi. Withdrawn by PI:
     Reason(Give details):
   - vii. Active on treatment:
   - viii. Completed treatment :
   - ix. Participants on follow-up:
   - x. Participants lost to follow up:
   - xi. Any other:
   - xii. Number of drop outs:
     Reasons for drop-out:

8. Total number of SAEs reported till date in the study:
Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes / No

9. Have there been participant complaints or feedback about the study? Yes / No
If yes, provide details:

10. Have there been any suggestions from the SAE Sub Committee? Yes /No
If yes, have you implemented that suggestion? Yes / No

11. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants): Yes No
If Yes, provide details:

12. Summary of results (if any):

Signature of PI. .....

(Dr. Suraj Agrawal)
Chairperson
IEC, GDC, Raipur

(Dr. Rajendra Kumar Dubey)
Member, Secretary
IEC, GDC, Raipur