Jawahar Medical Foundation's
ANNASAHEB CHUDAMAN PATIL MEMORIAL DENTAL COLLEGE
Address: Post Box No. 145, Sakri Road, Dhule (M.S) – 424 001
Tel: +91 – 256 - 200674
Fax: +91 – 256 – 202027
Email: jmfacpmdc@gmail.com

Ref No: 3765 /ACPMDC/ Dhule/ 22 **Date: 26.12.2022**

NOTICE

Subject: Regarding Constituting the Institutional Ethics Committee

This is to inform all the Head(s) / In charge(s) of the Departments, teaching faculty and Post Graduate students that the following Members have been constituted to form the Institutional Ethics Committee. All research projects to be undertaken in the institute are to be submitted for prior approval by the committee. All members are to submit their details in the prescribed format attached along with this letter.

Sr. No	Designation	Name of Member
1	**Chairperson**	Dr. Ajit Gajanan Pathak
2	**Member Secretary**	Dr. Prashanth Vishwakarma
3	**Basic Medical Scientist(s)**	Dr. Prashant Solanke
4		Dr.(Mrs.) Aarti Karnik-Mahale
5		Dr. Manish Sharma
6	**Clinician(s)**	Dr. Suresh Nagral
7		Dr. Anuradha Bhatsange
8		Dr. Chetan Vinay Deshmukh
9		Dr. Harish Jadhav
10	**Legal Expert(s)**	Adv. Chandrashekar P. Kulkarni
11		Adv, Rakesh Kakuste
12	**Social Scientist**	Mr. Sudam Gemi Rathod
13	**Lay Person(s)**	Mr. Santosh Ravan Patil
14		Mr. Swapnil B. Patil
15	**Supporting Staff(s)**	Mr. Bapu Bhimrao Kale
16		Mr. Sunil Somnath Shimpi
17		Mr. Amol Popatrao Patil

Copy to All Departments

J.M.F's A.C.P.M. DENTAL COLLEGE DHULE
SEAL

PRINCIPAL
ACPM Dental College,
Dhule

Principal,
J.M.F.'s A C P M Dental College,
DHULE - 424001 (M.S.)

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairperson: Ajit Gajanan Pathak, Shri. Bhausaheb Hire Govt Medical College , Dhule, Dhule, Maharashtra, India - 424001

2. Name and address of the office : of the Ethics Committee*: JMF ACPM DENTAL COLLEGE INSTITUTIONAL ETHICS COMMITTEE, JMF A C P M DENTAL COLLEGE, POST BOX NO 145 SAKRI ROAD DHULE, , DHULE, Dhule, Maharashtra - 424001
Contact No. : 2562277924 Fax No. : 2562279924

3. Names, address, qualifications & designation of all the members of the Ethics Committee*

S.No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail and mailing address	Designation/ role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Ajit Gajanan Pathak	MBBS (MD Forensic Medicine and Toxicology)	Shri. Bhausaheb Hire Govt Medical College	Mobile: 9823184554, email: ajitgpathak1@gmail.com Add: Staff Quarters, Dhule, Dhule, Maharashtra-424001	Chair Person	No
2	Dr. Prashanth Yachrappa Vishwakarma	BDS (MDS in Public Health Dentistry)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9766745627, email: dr_prashanthvk@yahoo.com Add: Staff Quarters No 12, ACPM Dental College, Dhule, Dhule, Maharashtra-424001	Member Secretary	Yes
3	Dr. Prashant Vinayak Solankhe	MBBS (MD in Community Medicine)	Jawahar Medical Foundations Annasaheb Chudaman Patil Memorial Medical College And Hospital, Dhule	Mobile: 9751926130, email: drprashantsolanke@rediffmail.com Add: New 10 Staff Quarters ACPM Medical College, Dhule, Dhule, Maharashtra-424001	Basic Medical Scientist	No
4	Dr. Aarti Karnik Mahale	MBBS (M.Sc., Ph. D. in Medical Biochemistry)	JMFs ACPM Medical College And Hospital, Dhule	Mobile: 7709542333, email: dr.aarti.biochem@gmail.com Add: Pitrudaya Apartment Sneh Nagar, Dhule, Dhule, Maharashtra-424001	Basic Medical Scientist	No

5	Dr. MANISH SHARMA	BDS (MDS in ORAL PATHOLOGY)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 8081259757, email: DRMANISHSHARMA2007@GMAIL.COM Add: STAFF QUARTER NO 11, DHULE, Dhule, Maharashtra-424001	Basic Medical Scientist	Yes
6	Dr. Suresh Nagaral	BDS (MDS in Prosthodontics and Crown and Bridge)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9595833155, email: drsurinagaral@gmail.com Add: Staff Quarters No 8, ACPM Dental College, Dhule, Dhule, Maharashtra-424001	Clinician	Yes
7	Dr. Harish Chaitram Jadhav	BDS (M.D.S. in Public Health Dentistry)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9881248105, email: drharishjadhav2003@gmail.com Add: 28 Govardhan Nagar, Dhule, Dhule, Maharashtra-424002	Clinician	Yes
8	Dr. Chetan Vinay Deshmukh	BDS (M.D.S. in Public Health Dentistry)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9665854346, email: drchetanvinaydeshmukh@gmail.com Add: Staff Quarters No. 10, ACPM Dental College, Dhule, Dhule, Maharashtra-424001	Clinician	Yes
9	Dr. Anuradha Bhatsange	BDS (MDS in Periodontology)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9960881275, email: anujaps219@gmail.com Add: Staff Quarters No 4, ACPM Dental College, Dhule, Dhule, Maharashtra-424001	Clinician	Yes
10	Dr. Sudam Gemu Rathod	BSW (M.S.W. and Ph.D.)	Dr. Babasaheb Ambedkar College Of Social Work, Dhule	Mobile: 9175022216, email: sudam_rathod@rediffmail.com Add: 103 Sai Apartments, General Arunkumar Vaidya Nagar, Dhule, Dhule, Maharashtra-424001	Social Scientist	No

11	Mr. Rakesh Subhash Kakuste	LLB (None)	Jawahar Medical Foundations Annasaheb Chudaman Patil Memorial Medical College And Hospital, Dhule	Mobile: 9672161160, email: kakuste@jmfacpm.com Add: 66 A Panzra Kan Colony, Sakri, Dhule, Maharashtra-424304	Legal Expert	No
12	Mr. Chandrasheka r Purushottam Kulkarni	LLB (Master of Laws (LL.M.))	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9422753857, email: mr.c.p. kulkarni@gmail.com Add: 1311 A, Dhule, Dhule, Maharashtra-424001	Legal Expert	Yes
13	Mr. Santosh Ravan Patil	BA (Not Applicable)	JMFs ACPM Medical College And Hospital, Dhule.	Mobile: 9422737794, email: santoshrp1979@gmail.com Add: C/o Ravan, Chakkar Bardi Road, Near Shiv Mandir, Dhule, Dhule, Maharashtra-424001	Lay Person	No
14	Mr. Swapnil Bhalerao Patil	BA (Not Applicable)	JMFs ACPM Medical College And Hospital, Dhule	Mobile: 9403762162, email: swapnilbpatil450@gmail.com Add: Plot. No 71 B Krushna Nagar, Dhule, Dhule, Maharashtra-424002	Lay Person	No
15	Mr. Amol Popatrao Patil	BA (Not Applicable)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9158484437, email: patilamol3399@gmail.com Add: At Hadsune Post Vellhane, Dhule, Dhule, Maharashtra-424311	Other Supporting Staff	Yes
16	Mr. Bapu Bhimrao Kale	BSc (B.Ed)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9011298858, email: Bapukale503@gmail.com Add: At Post, Dhule, Dhule, Maharashtra-424301	Other Supporting Staff	Yes

17	Mr. Sunildutt Somnath Shimpi	B. COM (M.Com)	JMFS A.C.P.M. DENTAL COLLEGE	Mobile: 9420440608, email: sunilshimpi74@gmail.com Add: At Post Kusumba, Dhule, Dhule, Maharashtra-424302	Other Supporting Staff	Yes

4. Commitments:

(1) The Committee shall review and accord its approval to a biomedical research and also carry ongoing review of the study at appropriate intervals, as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants - ICMR for safeguarding the rights, safety and well- being of the research participants.

(2) In case of any serious adverse event occurring to research participants during the research study, the Committee shall analyze and forward its opinion as per procedures specified under National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

(3) The Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of biomedical and health research.

(4) We agree to maintain adequate and accurate records after the completion or termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies).

(Signature of the Chairperson)

Date : 26.12.2022

V.K. Pradhan

(Signature of the Member secretary)

Date : 26/12/22

FORM CT-01

(See rules 8, 10 and 17)

APPLICATION FOR REGISTRATION/RENEWAL OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY OR BIOMEDICAL HEALTH RESEARCH

I/We, Dr. ARUN SURESH DODAMANI (Principal) , Opp Jawahar Soot Girni, Sakri Road, Dhule Dhule Dhule, Maharashtra - 424001 (India) of JMF ACPM DENTAL COLLEGE INSTITUTIONAL ETHICS COMMITTEE Room No. 8 Floor No. 3 Building No. JMF ACPM DENTAL COLLEGE , JMF A C P M DENTAL COLLEGE, POST BOX NO 145 SAKRI ROAD DHULE, , DHULE, Dhule, Maharashtra - 424001 Telephone No.: 2562277924 FAX: 2562279924 hereby apply for grant of registration of ethics committee.

The details of the application are as under:

1. Name of Applicant:	Dr. ARUN SURESH DODAMANI
2. Nature and constitution of applicant:	Private
3. (i) Applicant address :	Opp Jawahar Soot Girni, Sakri Road, Dhule Dhule Dhule, Maharashtra - 424001 (India)
(ii) Address for correspondence :	M/s JMF A C P M DENTAL COLLEGE, POST BOX NO 145 SAKRI ROAD, DHULE , Maharashtra, (India) - 424001 Telephone No.: 2562277924 FAX: 2562279924

4. Details of accreditation, if any (self-attested copy of certificate to be attached): null

5. I have enclosed the documents as specified in the Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019.

6. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Digital/Physical Signature

Date: 02-Nov-22

Place:

(Name and Designation)

Name: **Dr. Arun S. Dodamani**

Destination: **Principal,**
J.M.F's A.C.P.M. Dental College
Dhule. (Maharashtra)

SEAL

Jawahar Medical Foundation's

ANNASAHEB CHUDAMAN PATIL MEMORIAL DENTAL COLLEGE, DHULE

Add: Sakri Road, Opp. Jawahar Sootgirni, Dhule (Maharashtra State) PIN 424001

Contact Number: 02562-277924 E-mail: jmfacpmdc@gmail.com

STANDARD OPERATING PROCEDURES

(SOP)

For

INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures (SOP)

for

Institutional Ethics Committee (IEC)

Jawahar Medical Foundation's

ANNASAHEB CHUDAMAN PATIL MEMORIAL DENTAL COLLEGE, DHULE

Sakri Road, Dhule (Maharashtra State) PIN 424001

Version: 01

Date: 02.11.2022

(Valid for a period of 5 years from the date of print or earlier as decided by the Committee and / or Parent Insitute)

SOP Prepared by:

I. Dr. Manish Sharma

Professor, Dept. of Oral Pathology, J.M.F's A.C.P.M. Dental College, Dhule.

Member, Institutional Ethics Committee, J.M.F's A.C.P.M. Dental College, Dhule.

II. Dr. Chetan Vinay Deshmukh

Assistant Professor, Dept. of Public Health Dentistry, J.M.F's A.C.P.M. Dental College, Dhule.

Member, Institutional Ethics Committee, J.M.F's A.C.P.M. Dental College, Dhule.

Approved by:

III. Principal

J.M.F's A.C.P.M. Dental College, Dhule.

IV. Dr. Arun Wamanrao Patil

Chairperson, Institutional Ethics Committee, J.M.F's A.C.P.M. Dental College, Dhule

V. Dr. Prashanth Vishwakarma

Member Secretary, Institutional Ethics Committee, J.M.F's A.C.P.M. Dental College, Dhule

CONTENTS:

INTRODUCTION:

Jawahar Medical Foundation's Annasaheb Chudaman Patil Memorial Dental College is one of the premier institutes in Dental Education, situated in Dhule city, a prominent place in the Khandesh region of Maharashtra State. The institute was founded in 2002 in line with the vision of Late Shri Annasaheb Chudaman Patil, of providing state-of-the-art medical and dental education as well as medical and dental services in highly concessional fees and charges. The institute prides itself in being one of the few private dental institutes that charges the least fees to its students for education and provides maximum outreach programs to the underprivileged regions including the remotest tribal villages in North Maharashtra. The Insitute also adheres to a strict quality standard in providing best dental education to its undergraduate, postgraduate as well as doctorate students and also in ensuring the best premium dental treatment services to the patients.

A.C.P.M. Dental College is an institute by the Dental Council of India and affiliated with the Maharashtra University of Health Sciences, Nashik. The institute has an annual intake capacity of 100 undergraduate B.D.S students and a total of 29 postgraduate students across 7 specialties. In association with the Maharashtra University of Health Sciences, Nashik; the Insitute has been approved as centre for Doctor of Philosophy (Ph.D.) Research offering Ph.D. in two specialties currently and tentatively more in the near future. With this growing rapid developing pace, A.C.P.M. Dental College aims to develop itself into an institute of eminence with respect to research to develop innovative therapies, devices and concepts to deliver better services which are patient-focussed healthcare that is readily accessible, cost effective and meets the needs of the communities.

Bio medical research involves a number of ethical issues that need to be addressed. The Institutional Human Ethics Committee (IHEC)/IEC plays an important role in guiding researchers in the ethical aspects associated with the biomedical research.Apart from ethical issues,IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines).

OBJECTIVES:

The objective of compiling this Standard Operating Procedure or SOP is to maintain effective functioning of the Institutional Ethics Committee (IEC) and to ensure quality and technical excellence and consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019.

The basic responsibility of the IEC is to ensure a competent review of all the ethical aspects of the research proposals and ensure they are executed in the same manner free from any bias and influence that can affect the objectivity of the study. The IEC shall also provide credible scientific as well as ethical advice to the researchers on all the aspects of welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committees. The scientific evaluation should ensure the technical excellence of the proposed study.

The responsibilities of the IEC can be defined as follows:

I. To protect the dignity, rights and well being of the potential research participants.

II. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customer.

III. To assist in the development and the education of a research community responsive to local health care requirements

IV. The ethics committee should exercise particular care to protect the rights, safety and wellbeing of all vulnerable subjects participating in the study.

It is hence highly expected that the members of the Institutional Ethics Committee be well versed with the provisions of Clinical trials under the Drugs and Cosmetics Act, 1945; Good Clinical Practice Guidelines for Clinical Trials in India and other regulatory acts which are essential requirements to safeguard the rights, safety and well being of the trial participants.

AUTHORITY UNDER WHICH THE IEC IS CONSTITUTED:

The ACPMDC - Institutional Ethics Committee (ACPMDC - IEC) is an Institutional Ethics Committee which functions independently. The Principal of the Dental College in consultation with the authorities from the Hon'ble Management (Jawahar Medical Foundation, Dhule) will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of the IEC members will be for 3 years or till further orders.

COMPOSITION:

The Institutional Ethics Committees are characterised as being multi-disciplinary and multi-sectoral in composition with independence and competence being its two hallmark of effective functioning. The IEC shall consist of not less than 7 members and the Chairperson of the Ethics Committee shall not be affiliated to the parent institute.

As per the ICMR National Ethical Guidelines2017, ACPMDC- IEC should have the following categories of members:

A. Chairperson – Non affiliated to the parent Insitute.

B. Member Secretary- Affiliated

C. Basic medical scientist(s)-Non-affiliated/affiliated

D. Clinician(s) - Non-affiliated / Affiliated

E. Legal expert(s)- Non-affiliated / Affiliated

F. Social Scientist/NGO Representative/Philosopher/Ethicist/Theologian-Non-affiliated/ Affiliated

G. Lay person from the community - Non-affiliated / Affiliated

Besides these, subject experts can be invited to attend the proceedings of the committee. However such subject experts shall only be consultative and shall be devoid of voting rights.

QUORUM REQUIREMENT:

As per the revised Schedule Y Drugs and Cosmetics (Second Amendment), Ministry of Health and Family Welfare, New Delhi 2005 and Drugs and Cosmetics Act (Third Amendment) Rules 2013 Notification dated 8th Feb 2013 (Rule 122DD), the Ethic Committee approving Clinical Trials should have in the quorum at least one representative from the following groups:

I. One Basic Medical Scientist

II. One Clinician

III. One Legal Expert

IV. One Social Scientist / Representative of Non Governmental Organisation / Philosopher / Ethicist / Theologian or a similar person.

V. One Lay person from the community.

Also to be followed with respect to the quorum requirement,

I. A minimum of five members must be present in the meeting room.

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

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

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

V. The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.

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

RESPONSIBILITIES OF THE MEMBERS OF THE IEC:

The main responsibility of ACPMDC-IEC is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals. It should ascertain that all ethical principles of research such as Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research.IEC will review each study proposal for its both scientific and ethical review.

Members of IEC are expected to attended all IEC meetings and prior information should be provided if a member is unable to attend meeting.

Responsibilities of each member is mentioned below

I. Chairperson – Non affiliated to the parent Insitute.

- Conduct IEC meetings and ensure active participation of all members during meeting
- Ratify minutes of the previous meetings
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, IEC members, conflict of interest issues and requests for use of IEC data, etc.

II. Member Secretary- Affiliated

- Organise an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule IEC meetings, prepare the agenda and minutes
- Organise IEC documentation, communication and archiving

- Ensure training of IEC secretariat and IEC members
- Ensure SOPs are updated as and when required & adherence of IEC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

III. Basic medical scientist(s)-Non-affiliated/affiliated

- Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmacodynamics in case of clinical trials

IV. Clinician(s) - Non-affiliated / Affiliated

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report).
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure & all other protocol details.

V. Legal expert(s)- Non-affiliated / Affiliated

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher’s undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc) compliance with guidelines etc.

VI. Social Scientist/NGO Representative/Philosopher/Ethicist/Theologian-Non-affiliated/ Affiliated

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

VII.Lay person from the community - Non-affiliated / Affiliated

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

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

All IEC members must be familiarised with guidelines related to research and ethics such as ICMR National Ethical Guidelines 2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines. When there is any change in SOP the same will be communicated to the members and necessary training will be imparted.Record will be maintained regarding the training of members and change in the SOP/guidelines.

Members are expected to declare conflicts of interest, if any, before commencement of the meeting.IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest.

The IEC has the rights to revoke its approval accorded to scientific study/clinical study protocol, and further, it has to record the reasons for doing so and communicate the same to the

Investigator as well as to the Licensing Authority/ other relevant stakeholders. IEC may review progress of the approved studies periodically till the completion of the study through periodic study progress report /internal audit reports. The investigator is responsible for reporting all SAEs including hospitalisation or prolongation of hospitalisation, clinical trial related injury or death, regardless of causal relationship to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication(including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days.SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days).

The IEC shall forward the report on any SAE(including, death), after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority.The copy of the report has to be submitted the Licensing Authority within twenty one calendar days of the occurrence of the SAE.

REQUIREMENTS FOR THE IEC MEMBERSHIP:

- Every IEC member must:
- Provide an updated CV with signature
- Consent letter
- Submit training certificates on human research participant protection and good clinical practice (GCP) guidelines.
- If not trained must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy)
- Be willing to undergo training or update their skills/knowledge during their tenure
- Declare Conflict of Interest (COI)in accordance with the policy of the IEC, if applicable, at the appropriate time
- Sign a confidentiality and conflict of interest agreement/s;

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

TERMS OF REFERENCE OF THE COMMITTEE:

I. **Appointment and Duration:**

The members will be appointed as by Nomination, for not more than a period of three years (3 years). This can be extended in exceptional situations after passing a resolution by the IEC and approved by the Principal of the dental college. One third of the total number may be replaced by newer members after the completion of the tenure of the previous members.

II. **Policy for Removal / Replacement:**

The Principal of the Dental college, on the recommendation of Chairperson and Member Secretary can remove or replace a member of the IEC under the following conditions:

A. Remaining absent in 2 consecutive meetings of IEC without any prior communication.

B. Expressing unwillingness to continue in the committee.

C. Performing any such acts in violation of the principles of the IEC.

Note: The Principal, in certain exceptional circumstances, on the recommendation of, or in consultation with the Chairperson and Member Secretary of the IEC can also substitute on a temporary basis, for a member who is unable to attend meetings temporarily, due to any illness or any other unfortunate unforeseen event. However, the person thus temporarily deputed must be of equivalent professional stature, education qualifications and experience as the member substituted.

III. **Resignation:**

Any member can choose to voluntarily resign from the membership of the IEC by submitting an application stating the same addressed to the Chairperson of the IEC with a copy to the Principal of the Dental College. Unless in emergency situations, the members shall submit the resignations at least 15 days before the next meeting, in order to appoint a suitable replacement.

IV. **Frequency of Meetings:**

The IEC shall convene for a meeting within four weeks of receiving a research proposal and submission of the study related documents or as required in emergency / exceptional situations. The responsibility for announcing and scheduling the meeting, preparing the agenda and

minutes of the meeting and informing the decisions and resolutions of the IEC to the Principal of the Dental College, lies with the Member Secretary.

V. **Levying of charges for Ethics Committee review process:**

The motive of the Institutional Ethics Committee is to ensure that a fair and transparent process is put in place for conduct of Biomedical Research. In accordance with this motive and objective, the Institutional Ethics Committee shall not, indulge in any commercial or profit making interests. However, the IEC can charge a reasonable fees to cover the expenses to review and for administrative purposes. The fees, if applicable, shall be decided upon by the IEC and shall be conveyed to the investigators as required. The IEC can also charge additional fees for research proposals that are submitted by researchers who are not affiliated to the institute. All research proposals/clinical trials funded / sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee / processing fee of 5% of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organisations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organisations etc.

VI. **Honorarium towards the IEC members:**

The non-affiliated members of the IEC are entitled to a basic honorarium for sparing their invaluable time towards conducting the review process. The terms of the suitable amount shall be decided upon at the time of appointment of the members of the IEC with the Principal of the Dental College.

Supporting Staff are also entitled for a suitable honorarium as per meetings of the IEC. All the financial aspects (review fees and honorarium) will be approved by the Principal of the institute from time to time.

VII. **Storage and archiving of all the documents:**

All the documents pertaining to the Institutional Ethics Committee will be kept in the office of the Member Secretary of the Ethics Committee with all required facilities. All the documents shall be archived carefully with the strictest levels of confidentiality. Terms of reference will be maintained in the office of IEC. This includes

1. MembershipRequirements
2. Terms of Appointment with reference to the duration of the term,

3. The policy for removal, replacement, resignation procedure,

4. Frequency of meetings, and

5. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage (35 to 50%) of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country.

CONVENTION & CONDUCT OF THE MEETING:

The Chairperson will conduct all meetings of the ACPMDC-IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting. The alternate or acting chairperson should have the powers of the chair person for the duration of the meeting and hence, should be a non-affiliated person. The Member Secretary is responsible for organising the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. In the absence of Member Secretary alternate Member Secretary among the members, will organise the IEC meeting. All proposals will be received at least 2 weeks before the meeting and after initial scrutiny by Member Secretary the proposals will be circulated to the IEC members. The recommendations by the IEC will be communicated to all the Primary Investigators and to the Postgraduate Guides and Head of the Departments in case of student's proposals. If required additional review meetings can also be conducted with a short notice period in exceptional or extraordinary circumstances.

APPLICATION PROCEDURE:

All proposals should be submitted to IEC on any working day 3 weeks in advance of scheduled meeting in the prescribed application form along with relevant documents. Eight (8) hard Copies soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / should be submitted to IEC Principle Investigators shall be forwarded their application to the Chairperson

IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. IEC can suggest for online meetings and virtual presentations of the investigators in special situations such as COVID-19 pandemic, etc.

If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

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

DETAILS OF THE DOCUMENTS TO BE INCLUDED IN THE PROTOCOL:

The protocol should include the following:

I. The first page carrying the title of the proposal with signatures of the investigators;

II. Brief summary/ lay summary of the protocol;

III. Background with rationale of why a human study is needed to answer the research question;

IV. Justification of inclusion/exclusion of vulnerable populations;

V. Clear research objectives and end points/ outcome ;

VI. Eligibility criteria and participant recruitment procedures;

VII. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomised, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;

VIII. Duration of the study;

IX. Justification for use of placebo, benefit–risk assessment, plans to withdraw and rescue medication. If standard therapies are to be withheld,

X. Procedure for seeking and obtaining written informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Informed consent for storage of samples;assent; re-consent

XI. Plan for statistical analysis of the study;

XII. Plan to maintain the privacy and confidentiality of the study participants;

XIII. For research involving more than minimal risk, an account of managementof risk or injury; Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period and insurance policy

XIV. Provision of ancillary care for unrelated illness during the duration of research;

XV. An account of storage and maintenance of all data collected during the trial; and

XVI. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.

XVII. Ethical considerations and safeguards for protection of participants

REVIEW PROCEDURES:

The IEC shall review every research proposals on human participants only and only BEFORE the research is initiated. Under no circumstances, shall IEC review procedure take place after the research has been initiated. It shall ensure that a scientific evaluation, including facilities and infrastructure of study sites, justification of placebo in control group, has been completed by the members of the IEC before keeping the proposal for ethics review. The committee shall evaluate the possible risks to the participants with proper justification, the expected benefits and the adequacy of documentation for ensuring privacy, confidentiality and the justice issues. Experimental new clinical entities (NCEs) need to be approved by the Drugs Controller General of India. It will be mandatory for the Primary investigator to submit the copy of the same. No proposal shall be considered for review if the DCGI permission is applied for / pending.

For all sponsored studies conducted at the Dental College, it will be mandatory for the Principal Investigator to submit a 'No Objection Certificate' from the concerned Head of the Department and the Principal of the Dental College. Without the NOCs, the proposals shall not be accepted.

Details of the compensation to be paid to the subjects / family if suffered from Serious Adverse Events (SAEs) will be required as a part of the proposal.

The IEC stands clear that proposals with incomplete information/documents will NOT be considered for review procedure. Similarly the proposals submitted must be paginated and the total number of pages need to be mentioned in the title page of the protocol.

The committee shall also be authorised to review and monitor the progress of th approved research and when thought to be necessary and shall maintain a list of proposals submitted / approved / rejected and their respective outcomes.

I. The meeting of the IEC will be held periodically, unless otherwise specified by the member secretary. Additional review meetings canal so be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

II. The proposals should be sent to the IEC at least 3 weeks in advance of scheduled meeting.

III. The Member-Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved categorise them into three types, namely, exemption from review, expedited review and full committee review.

IV. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.

V. The Primary Investigator / Research Scholar will then present the proposal in person in the meeting.

VI. When the Primary Investigator / Research Scholar is not available due to unavoidable reasons the Co-Primary Investigator / Research Scholar will be allowed to present the proposal. Researchers will be invited to offer clarifications on case to case basis, if needed.

VII. The review discussions/ decisions will be charted down and the final minutes will be approved by the Chairperson.

VIII. After the IEC meeting, the decision of the IEC members regarding the discussed proposals to be obtained on the same day of the meeting.

IX. The proceedings of the meeting can be video recorded with prior permission from all the members attending the meeting.

X. The type of EC review based on risk involved in the research, is categorised as follows:

A. Less than minimal risk:

Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc

B. Minimal risk:

Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

C. Minor increase over minimal risk or Low risk:

Increment in probability of harm or discomfort is only a little more than theminimal risk threshold.

- Routine research on children and adolescents; Research on persons incapable of giving consent
- Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomised trials;
- Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing;
- Trying a new diagnostic technique in pregnant and breastfeeding women etc.

- Research should have a social value. Use of personal identifiable data in research also imposes indirect risks.

- Social risks, psychological harm and discomfort may also fall in this category.

D. More than minimal risk or High risk:

Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk.

Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

The IEC Member Secretary or any other member nominated by the committee shall screen the proposals for their completeness and depending upon the risk involved, categorise them into three types namely:

1. Exemption from review:

Proposals which present “less than minimal risk” fall under this category. Following situations may come under this “less than minimal risk” category:

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

Exceptions:

1. 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.

2. When interviews involve direct approach or access to private papers.

2. Expedited Review:

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

1. Minor deviations from originally approved research protocol during the period of approval.

2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

3. Research activities that involve only procedures listed in one or more of the following categories •

A. Clinical studies of drugs and medical devices only when -

- Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
- Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is
  reported.
- Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
- When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

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

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

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

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

iv. If Data SafetyMonitoring Board (DSMB) is constituted to review the data;

C. Research on disaster management

It may also be unethical sometimes not to do research during disaster. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

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

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

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

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

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

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

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

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

3. Full Review:

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

a. Research involving vulnerable populations, even if the risk is minimal;

b. Research with minor increase over minimal risk

c. Studies involving deception of participants;

d. 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;

e. 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;

f. Major deviations and violations in the protocol;

g. 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;

h. 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;

i. Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

4. Interim Review:

The IEC can decide the extraordinary special circumstances and the mechanism when an interim review can be resorted to instead of waiting for the scheduled time of the meeting. However, decisions taken should be brought to the notice of the main committee. This can be done for the following reasons:

1. Re-examination of a proposal already examined by the IEC.
2. Research Study of a minor nature such as examination of case records etc.
3. An urgent proposal of national interest.

REVIEW OF RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATIONS:

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so and are incapable of providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years);women in special situations; tribals and marginalised communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatising or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Individuals may be considered to be vulnerable if they are:

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

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

compromised position to protect their interests on their own.

Principles of research among vulnerable populations to be followed as guidelines by the IEC:

- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

  Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and well- being of these individuals.

Additional safeguards/protection mechanisms

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate

- Researchers must justify the inclusion of a vulnerable population in the research.
- The IEC must satisfy themselves with the justification provided and record the same in the proceedings of the IEC meeting.
- Additional safety measures should be strictly reviewed and approved by the IEC.
- The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured.
- IEC should also carefully determine the benefits and risks of the study and examine the risk minimisation strategies.
- As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
- Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.
- Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
- Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.
- Efforts should be made to set up support systems to deal with associated medical and social problems.
- Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.
- Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counselling centre.

Obligations/duties of stakeholders:

All stakeholders have different responsibilities to protect vulnerable participants. They are enumerated as follows:

Stakeholders	Obligations / Duties
Researchers	• Recognise the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalised individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.
IEC	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimisation strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • IEC shall have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.
Sponsor(s)	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

Women in special situations

Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomy of the woman is important, the researcher

must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community.

Researchers must provide the IEC with proper justification for inclusion of pregnant and nursing women in clinical trials designed to address the health needs of such women or their foetuses or nursing infants. Some examples of justifiable inclusion are trials designed to test the safety and efficacy of a drug for reducing perinatal transmission of HIV infection from mother to child, trial of a device for detecting foetal abnormalities or trials of therapies for conditions associated with or aggravated by pregnancy, such as nausea, vomiting, hypertension or diabetes. If women in the reproductive age are to be recruited, they should be informed of the potential risk to the foetus if they become pregnant. They should be asked to use an effective contraceptive method and be told about the options available in case of failure of contraception.

A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the foetus. The matter should be carefully reviewed and she must be offered the option to withdraw or continue. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.

Prenatal diagnostic studies – research related to prenatal diagnostic techniques in pregnant women should be limited to detecting foetal abnormalities or genetic disorders as per the Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, amended in 2003 and not for sex determination of the foetus.

Research on sensitive topics – when research is planned on sensitive topics, for instance, domestic violence, genetic disorders, rape, etc., confidentiality should be strictly maintained and privacy protected. In risk mitigation strategies, appropriate support systems such as counselling centres, police protection, etc. should be established. At no time should information acquired from a woman participant be unnecessary, hurtful or appear voyeuristic. The IEC should be especially vigilant regarding these sensitive issues.

Children

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they

do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ LAR in the best interests of their child/ward. More details are available in ICMR "National Ethical Guidelines for Bio-Medical Research involving Children, 2017". The researcher, members of IEC and others concerned must go through the same if required.

Children can be included in research if the situation, condition, disorder or disease fulfils one of the following conditions:

I. It is exclusively seen in childhood.

II. Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.

III. Both adults as well as children are involved in a similar manner and are of similar nature in terms of morbidity, severity and/or mortality, wherever relevant, and studies in adults have demonstrated the required degree of safety and efficacy.

IV. Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention.

V. Risk of test interventions that is not intended to benefit the individual child participant is low as compared to the importance of the knowledge expected to be gained (minor increase over minimal risk).

VI. Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means.

VII. The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults. The absorption of drugs also varies with age. Pharmacokinetics and toxicity profile varies with growth and maturation from infancy to adulthood.

VIII. The adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children.

IX. Age appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children.

X. The pathophysiology of many disorders is dependent on a child's growth, development and adaptive plasticity. Examples include adaptive changes in the motor system following a perinatal stroke

The IEC should do the benefit–risk assessment to determine whether there is a need to put into place additional safeguards/protections for the conduct of research in children. For example, research should be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support.

The IEC should take into consideration the circumstances of the children to be enrolled in the study including their age, health status, and other factors and potential benefits to other children with the same disease or condition, or to society as a whole.

Consent of the parent/LAR is required when research involves children. See Box 6.5 for further details.

Assent

In addition to consent from parents/LARs, verbal/oral or written assent, as approved by the IEC, should be obtained from children of 7–18 years of age. As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures, that the child understands the request to participate in the research. A child's agreement to participate in research is called assent. If the child objects, this wish has to be respected. At the same time, mere failure to object should not be construed as assent. However, if the test intervention is likely to be lifesaving and is available only if the child participates in the study, the dissent by the child may be disregarded provided parental consent and prior approval from the IEC is obtained.

Content of the assent form has to be in accordance with the developmental level and maturity of the children to be enrolled and explained while considering the differences in individual understanding. The language of the assent form must be consistent with the cognitive, social and emotional status of the child. It must be simple and appropriate to the age of the child. Points to be included in the assent form are as given below:

- an explanation about the study and how it will help the child;
- an explanation of what will be done in the study, including a description of any discomfort that the child is likely to feel;
- the contact information of the person whom the child can approach if she/ he needs an explanation; and
- a paragraph emphasizing that the child can refuse to participate in the study and if she/he chooses to do so, the treatment at the centre will not be compromised.

Waiver of assent:

All the conditions that are applicable to waiver of informed consent in adults also apply for waiver of assent in children. See section 5.7 for further details. If the available intervention is anticipated to definitely benefit the child but would be available only if the child participates in the study, waiver of assent could be allowed. However, this situation should be accepted only in exceptional cases where all forms of assent/consent have failed. In such cases, approval of the EC should be obtained.

Consent of parent/LAR

The EC should determine if consent of one or both parents would be required before a child could be enrolled.

Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.

Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.

When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.

Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.

Research involving institutionalised children would require assent of the child, consent of parents/ LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

Considerations for assent

- There is no need to document assent for children below 7 years of age.
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
- Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the IEC, for example, in behavioural studies in IV drug users where parental consent may not be possible.

Research involving sexual minorities and sex workers:

- There are unique challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability.

- Protection of their dignity and provision of quality healthcare under these circumstances should be well addressed in the research proposal, preferably in consultation with the community before the proposal is finalised.

- It would be advisable to have a representative of the sexual minority group/ lesbian/ gay/bisexual and transgender (LGBT) community as a special invitee/member to participate in the meeting of the IEC if there is a research proposal involving these participants.

- The IEC can suggest setting up of a community advisory board to act as an interface between the researcher(s) and the community.

- Among the LGBT community there are inhibitions between the different groups, so details of the research should be explained to each group separately.

- Peer educators or champions among the LGBT community could be educated and sensitised first. They would in turn explain the details to the potential participants from the community who would then understand them better.

Research among tribal population

Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the tribal population.

Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector, should be taken before entering tribal areas.

Whenever possible, it is desirable to seek help of government functionaries/local bodies or registered NGOs who work closely with the tribal groups and have their confidence.

Where a panchayat system does not exist, the tribal leader, other culturally appropriate authority or the person socially acceptable to the community may serve as the gatekeeper from whom permission to enter and interact should be sought.

Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses.

Even with permission of the gatekeeper, consent from the individual participant must be sought.

Additional precautions should be taken to avoid inclusion of children, pregnant women and elderly people belonging to particularly vulnerable tribal groups (PVTG).

Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialisation.

Research involving individuals with mental illness or cognitively impaired/affected individuals

Mental illness: According to the World Health Organization, mental disorders comprise a broad range of problems, with different symptoms. They are generally characterised by some combination of abnormal thoughts, emotions, behaviour and relationships with others. According to the Mental Healthcare Act, 2017,[26] "mental illness" means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, capacity to recognise reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of the mind of a person, specially characterised by subnormality of intelligence. Presence of a mental disorder is not synonymous with incapacity of understanding or inability to provide informed consent.

Cognitively affected or impaired: Conscious mental activities such as thinking, understanding, learning and remembering are defined as cognition. Those in whom these activities are not fully functional are regarded as cognitively impaired. Such individuals or groups include people who are without full intellectual potential (intellectually disabled, previously called mentally retarded), unconscious, suffering from a number of neuropsychological disorders such as dementia or delirium, and those who cannot fully comprehend or participate in the informed consent process, either temporarily or permanently. Other sources or reasons for cognitive impairment affecting the ability to give informed consent include, but are not limited to, being too young (children do not yet develop the necessary cognitive abilities to give informed consent); being in extreme pain; being

under the influence of medication, illicit drugs or alcohol; mental retardation; and traumatic brain injury (that causes unconsciousness or cognitive impairment while conscious).

There are some psychiatric conditions that may lead people to cause risk or harm to themselves or others. During the informed consent process, prospective participants must be informed about how the researcher will address a participant's suicidal ideation or other risks of harm to themselves or others. It should be disclosed to the participant that her/his confidentiality may be breached for reporting to family members, police, or other authorities or they may have to be admitted in the hospital upon expression of such thoughts of harm to self or others. While some interventions, like hospitalization and treatment for suicidality/ homicidal ideas, may be primarily for the participants' own benefit, they themselves may not perceive these as such and may want to refuse to participate in a study if any such interventions are required. Interventions should be of short duration, as least restrictive as possible and invoked only when necessary, in accordance with relevant laws. Some research designs may reduce or violate human participant protections/rights or specific requirements of informed consent by resorting to deception in order to achieve the objectives of the research for public good. Types of deception that can be used in a research plan are described in Box 9.5. All such studies should be reviewed by the EC very carefully before approval.

Individuals who have diminished autonomy due to dependency or being under a hierarchical system:

While reviewing protocols that include students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, and others the EC must ensure the following:

- Enrolling participants as described above is specifically pertinent to the research questions and is not merely a matter of convenience.
- Individuals in a hierarchical position may not be in a position to disagree to participate for fear of authority and therefore extra efforts are required to respect their autonomy.
- It is possible for the participant to deny consent and/or later withdraw from the study without any negative repercussions on her/his care.

- Mechanisms to avoid coercion due to being part of an institution or hierarchy should be described in the protocol.

Patients who are terminally ill

Terminally ill patients or patients who are in search of new interventions having exhausted all available therapies are vulnerable as they are ready to give consent for any intervention that can give them a ray of hope. These studies are approved so that the scientific community or professional groups do not deny such patients the possible benefit of any new intervention that is not yet validated. Since therapeutic misconception is high there should be appropriate consent procedures and the IEC should carefully review such protocols and recruitment procedures. Additional monitoring should be done to detect any adverse event at the earliest. Benefit-risk assessment should be performed considering perception of benefits and risks by the potential participant. The IEC should carefully review post-trial access to the medication, especially if it is beneficial to the participant.

Other vulnerable groups

Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations. Additional precautions should be taken to avoid exploitation/retaliation/ reward/credits and other inducements when such individuals are to be recruited as research participants. Autonomy of such individuals is already compromised and researchers have to justify their inclusion. The IEC have to satisfy themselves with the justification provided to include these participants and record the same in the proceedings of the IEC meeting. Additional safety measures suggested earlier in the guidelines should be strictly followed by the IEC. The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalisation. The IEC should also carefully determine the benefits and risks of the study and examine risk minimisation strategies.

IEC should carefully determine the benefits and risks of the study and examine the justification provided and risk minimisation strategies.

Additional safety measures should be strictly reviewed and approved by the IEC.

IEC must ensure that the informed consent process should be well documented and recording of assent in case of research studies involving children aged 7 to 18 years and re-consent, when applicable.

Informed consent from vulnerable populations may be obtained from LAR (Legally authorised representative)in presence of impartial witness after through explanation of risks and benefits.

All procedures need to be followed from this SOP in all clinical studies. Special care needs to be taken by the Primary Investigator and study team for the vulnerable populations.

Pregnant or nursing women should not be participants of any clinical trials except trials that are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants and for which women who are not pregnant or nursing would not be suitable participants.

Children will not be involved in research that could be carried out equally well with adults. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support.

Efforts must be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

Research on genetics should not lead to racial inequalities.

Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

Rights and welfare of mentally challenged and differently abled persons who are incapable of giving informed consent or those which behavioural disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the suited, need for participants, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented in a clear, precise manner devoid of any ambiguity.

Adequate justification is required for the involvement of participants such as prisoners, students, sub ordinates, employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

The observations and the suggestions of the IEC should be given in writing in unambiguous terms in such circumstances.

Special Audits will be done by the IEC members in these situations.

Review of multi-centric research

Multi-centre research is conducted at more than one centre by different researchers usually following a common protocol.

All sites are required to obtain approval from their respective IECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.

The IECs of all participating sites should establish communication with one another.

If any EC does not grant approval for a study at a site the reasons must be shared with other IECs and deliberated upon.

The EC can suggest site-specific protocols and informed consent modifications as per local needs.

Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

Common review for all participating sites in multi-centric research - In order to save time, prevent duplication of effort and streamline the review process, the IECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.

Common review process may be applied to research involving low or minimal risk, survey or multi-centric studies using anonymised samples or data or those that are public health research studies determined to have low or minimal risk.

The common review is applicable only for IECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval.

Independent consultant/Invited subject experts

Subject experts will be called to provide special review for selected research proposals, if required. They can give their opinion/specialised views but they do not take part during decision making by IEC members i.e. they shall not have voting rights in the review process of the IEC.

DECISION MAKING PROCESS:

The IEC should be able to provide complete and adequate review of the research proposals submitted to them. It should meet periodically at frequent intervals to review new proposals as and when submitted, evaluate annual progress of ongoing ones and assess final reports of all research activities involving human beings through a previously scheduled agenda whenever appropriate.

I. Members will discuss the various issues before arriving at a decision. The decision must be taken by a broad consensus. When consensus is not arrived at, the decision will be made by voting procedure.

II. Decision will be made only in meetings where quorum is complete.

III. Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.

IV. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.

V. Modified proposals will be reviewed by an expedited review through identified members.

VI. A member must voluntarily withdraw from the IEC. While making a decision on an application which evokes a Conflict of Interest, which should be indicated in wiring to the chairperson prior to the review and should be recorded so in the minutes.

VII. If one of the member has his / her own proposal for review, then the member should not participate when the project is discussed.

VIII. The Member Secretary shall then communicate the decision in writing to the Primary Investigator or Research scholar within two weeks after the meeting at which the decision was taken in the specified format.

IX. The Committee shall decide whether to recommend / reject / suggest modification for a repeat review. Reasons for rejection shall be given.

X. The IEC reserves the right to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.

XI. The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved mid-way or unequivocal results are obtained.

XII. In case of premature termination of the study, notification should include the reasons for terminating along with summary of results conducted till date.

XIII. The Principal investigator / Co-investigator can be invited to present the protocol and offer clarifications in the meeting OR proposals will be submitted to the quorum for opinion and views which will be communicated to the Primary Investors for explanations before considering for clearance. Representatives of the patient groups or interest groups can be invited during meeting to offer their view point.

XIV. **IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.**

XV. The following circumstances require the matter to be brought to the attention of the IEC:

A. Any amendment to the protocol from the originally approved protocol with proper justifications.

B. Serious and Unexpected Adverse events and remedial steps taken to tackle the same. It will mandatory to the Primary Investigator to forward this information of the Serious Adverse Event to the Drugs Controller General of India and other such regulatory authorities involved within 24 hours. In case of any serious adverse event occurring to the participant of a clinical trial during the trial, the IEC shall analyse and forward its opinion as per procedures specified in the New Drugs and Clinical Trials Rules 2019.

C. Any new information that may influence the conduct the study.

XVI. The chairperson will appoint and permit other non affiliated member to act as chairperson for the meeting in his absence. The same should be noted in the minutes of the meeting.

XVII. Meetings are to be minuted by the member secretary of the IEC.

XVIII. The Chairperson will appoint member secretary to sign the approval letters. Minute of the meeting approved and signed by the Chairperson / Member Secretary will be circulated to the members in the subsequent meetings.

XIX. Attendance muster of meetings will be maintained by the member secretary.

XX. The communication of the decision will include:

A. Name and address of IEC.

B. The date, place and time of decision.

C. The name and designation of the applicant.

D. Title of the research proposal reviewed.

E. The clear identification of protocol no., version no., date, amendment no., date.

F. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.

G. List of EC members who attended the meeting- clear description of their role, affiliation and gender.

H. A clear statement of decision reached.

I. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the ACPMDC IEC

J. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

K. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

L. Signature of the member secretary with date

Record keeping and archiving of documents

All Research proposals (8 hard copies along with soft copy) along with the information and documents submitted will be dated and filed. The documents will be archived for a minimum period of 5 years and for sponsored clinical trials for 8 years after completion/termination of the study.
IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

1. Constitution and Composition of the IEC
2. Standard Operating Procedures of the IEC
3. Curriculum Vitae & consent of IEC members
4. National and International Guidelines.
5. IEC Registration
6. All Correspondence with the IEC embers and investors regarding application, decision and follow up.
7. Honorarium details, Income and expenses
8. Agenda & minutes of the IEC meetings bearing the signature of the Chairperson and Member / Secretary.
9. One copy of proposal
10. Copy of recommendations/decision communicated to applicant
11. Review reports, documents received during the follow up period and final reports of the study.
12. Record of all notifications issued for premature termination of a study with summary of the reasons.

13. Final report of the study including microfilms, CDs and video recordings, etc. will be maintained after receiving he same.

Responsibilities of a Principal Investigator:

The committee expects from the Principal Investigator:

1. A report of the clinical trial on a monthly basis.

2. A report of each serious event observed during the conduct of the study within the time frames. The Principal Investigator should submit the SAE to sponsors in case of sponsored study to be forwarded to the DCGI and measures taken to resolve the same. A copy of the same should be marked to the ACPMDC-IEC.

3. To be kept informed of the amendments with defined reasons made to any study related documents and get the approval of the same from the IEC before applying amendments.

4. To be kept informed about the study discontinuation with its reasons.

5. Mandatory to submit summary report after completion of the study.

6. No data or part of data should be used for publication till the study is completed and the Primary Investigator submits the study completion report of the same to the IEC.

7. No data / investigations / interventions will be done or recorded in the study participants other than approved by the IEC.

8. In case the above information is not submitted, then the Primary Investigator / Co-investigator / sponsors shall bee responsible during the audits by the authorities.

Submission of the Application:

- The Principal Investigator should submit an appropriate application in a prescribed format only.

- The Primary Investigator should submit one copy of complete protocol in the required format along with references, detail case-record form, compulsory appendices, and formats as required and other specific information together as one minded copy.

- In addition, separate seven copies of only synopsis (not more than 3-4 pages)

CONTENTS OF PROTOCOL:

It will be mandatory to prepare the protocol as per the Schedule Y guidelines. All the Heads as mentioned below must be covered and if not, suitable justification must be given for the same. No proposals shall be accepted if the details are not entered correctly.

1. Clear, precise and explanatory research title, details of background of the research, study objectives, study design, section criteria, study population, sample size, interventional product details in all perspectives, informed consent in vernacular languages as applicable, procures that will be followed, investigators, procedures of data recording, any tech information, data sand safety monitoring procedures as applicable.

2. For all the sponsored studies conducted at ACPM Dental College, it will be mandatory for the Principal Investigator to submit the 'No Objection Certificate' from the Head of the Department and Principal of ACPM Dental College Dhule. Without the NOCs, the proposals shall not be accepted for review.

3. All details of funding agency / sponsors / funds allocation / utilisation / patient remuneration / signed indemnity agreement / investigator's agreement with the sponsors, proposed compensation and reimbursement of incidental expenses. Undertaking in this regard by the PI and the concerned Sponsors will be compulsory.

4. CTRI Registration as applicable.

5. Permission Letters from licensing authorities (DCGI and others)

6. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.

7. A description of plans to withdraw or withhold standard therapies in the course of research.

8. Procedure for seeking and obtaining informed consent with samples of patient information sheet and informed consent forms in English and vernacular languages. (As specified in the Appendix V of Drugs and Cosmetics Act, 1945)

9. The detailed plans for statistical analysis of the study.

10. Statement of privacy and confidentiality of personal data.

11. Investigator’s Brochure.

12. Undertaking by the Investigator.

13. Recent curriculum vitae f the investigators, indicating qualification and experience.

14. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.

15. For research carrying more than minimal risk, an account of plans to provide medical therapy such risk or injury or toxicity due to overdose should be included.

16. SAE reporting format as applicable for all interventional studies as specified in the Appendix XI of the Drugs and Cosmetics Act, 1945 or other Pharmacovigilance Guidelines.

17. All details of the Funding agency / Sponsors and fund allocation / utilisation / patient remuneration / signed indemnity / investigators agreement with sponsors, etc. for the proposed work. Proposed compensation and reimbursement of incidental expenses. Undertaking in this regard of PI & Sponsor will be compulsory.

18. Storage and maintenance of all data collected during the trial.

19. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of study participants.

20. A statement on probable ethic issues and steps taken to tackle the same.

21. All other relevant documents related to the study protocol including regulatory clearances.

22. Agreement to comply with national and international GCP protocols for Clinical trials.

23. Detailed Case Record Form covering fine details of observation to be recorded.

24. A statement stating that No other data / investigators / interventions will be done or recorded in the study participants other than approved by the IEC.

25. For international collaborative study details about foreign collaborators and documents for review of Health Ministry’s Screening Committee (HMSC) or appropriate Committees under other agencies / authorities like the Drugs Controller General of India.

26. For exchange of biological material in international collaborative study, a MoU / Material transfer agreement between the collaborating partners.

27. A statement on Conflict of Interest, if any.

28. Any other relevant information is to be documented.

29. Complete photo copies of essential references.

VALIDITY OF APPROVAL & RE-APPROVAL OF STUDY:

IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

In case the study needs a further extension, the researcher may submit a truncated proposal with a request letter to the member secretary.

The member secretary shall scrutinise the application and on the basis of the justification given and on risk-benefit evaluation, shall determine the grant of re-approval.

Administration and management:

ACPM Dental College shall provide an office for the IEC which will have adequate space, infrastructure and staff to the EC for maintaining safe archival of records and conduct of meeting. A reasonable fee for review may be charged by the IEC to cover the expenses related to optimal functioning in accordance to Institutional policies for industry sponsored projects/funded projects. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

Web page for IEC:

A dedicated webpage will be created and maintained for IEC as a part of the institutional website. Details of composition, SOP ,registration details, circulars/notifications related to IEC meetings and status of submitted proposals and ongoing projects, submission forms, guidelines and contact details can be displayed on this page

Contact Details:

Name	:	Dr. Prashanth Vishwakarma
Designation	:	Member - Secretary
Address	:	Dept. of Public Health Dentistry, J.M.F's A.C.P.M. Dental College, Sakri Road, Dhule. 424 001
Contact No	:	(02562) 277924 Fax: (02562) 279924
E-mail	:	jmfacpmdc@gmail.com

ANNEXURES

Letter head

Letter ref no:

To

Dear Sir/Madam

Greetings from J.M.F's A.C.P.M. Dental College, Dhule

Sub: Invitation to be a member for Institutional Ethics Committee (IEC) of J.M.F's A.C.P.M. Dental College, Dhule

Based on your expertise in the field of medicine and research, you are cordially invited to be a member of our IEC for a period of three years or till further orders. I request you to kindly accept our invitation and confirm the same at the earliest.

This is issued with approval of competent authority.

With Regards

The Principal,

J.M.F's A.C.P.M. Dental College,

Sakri Road,

Dhule (Maharashtra State) 424 001

From:

To
The Principal,
J.M.F's A.C.P.M. Dental College,
Sakri Road,
Dhule (Maharashtra State) 424 001
Sub: Consent to be a member of Institute Ethics Committee (IEC) - Reg.

Ref: Your Letter No: dated:

Dear Sir/Madam

With reference to your letter stated above, I hereby extend my willingness to become a member of IEC of ACPM Dental College, Dhule. I shall regularly attend IEC meetings to review and give my unbiased opinion regarding the ethical aspects of research proposals involving human participants.

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

I shall not participate in quorum decisions where there is a conflict of interest.

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

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature with date

Name of the Member :

Address:

Telephone No: (Off) (Res) email:

Letter head

APPOINTMENT ORDER

Ref No:

Dr/ Mr. / Mrs.:

I am pleased to appoint you as the ---------- of the Institutional Ethics Committee (IEC) (Human research) at JMF's ACPM Dental College, Dhule following the receipt of your acceptance letter. The appointment shall be effective from --- for a period of _ year / months or till further notice provided the following conditions are satisfied.

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

Further, the renewal of your appointment will be by consensus & one-month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, JMF's ACPM Dental College Dhule

You will be paid a sum of INR/...../- per sitting as Honorarium for your services rendered towards attending the IEC meetings at JMF's ACPMDC as per the institutional norms.

We sincerely hope your association with IEC, JMF's ACPMDC will be scientifically productive and beneficial to the Institute & the community at large.

Signature with date

Date:

Application for Initial review

A. Basic information

(a) Title of the study:

Acronym/Shorttitle,(Ifany):

(b) Name of Principal Investigator:

(c)Department:

(d) Date ofsubmission:

(e) Designation:

(f) Email id:

(g)Typeofreviewrequested:

Exemption fromreview☐ Expedited review☐ Full committee review☐

(h) Protocol number (Ifany): Version number:

(i) Details ofInvestigators:

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

(i) Number of studies where applicant isa:

i) PrincipalInvestigatorattimeofsubmission

ii) Co-Investigator at time ofsubmission:

(k)Durationofthestudy:

FUNDING DETAILS ANDBUDGET

(a) Total estimated budget for site:

At site

Overall.

(b)Self-funding☐ Institutionalfunding☐ Funding agency *(Specify)*☐

SECTION B - RESEARCH RELATED INFORMATION

1. OVERVIEW OFRESEARCH

(a)Laysummary(within300words):

(b) objective of the study:

(c) Type of study:

BasicSciences	☐	Clinical	☐	CrossSectional	☐
Retrospective	☐	Epidemiological/	☐	CaseControl	☐
Prospective	☐	PublicHealth		Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
MixedMethod	☐	Any others*(Specify)*	☐		

(d) justification for conduct of this study:

1. METHODOLOGY

(a) Sample size/ number of participants

At site : total sample size

Control group / Study group

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

(b)Inclusion criteria:

(c) Exclusion criteria:

(d) Study design:

(e) Investigations specifically related to projects:

(f) Isthereanexternallaboratory/outsourcinginvolvedforinvestigations?Yes / No/ NA

(g) Howwasthescientificqualityofthestudyassessed?

Independent external review / Reviewbysponsor or Funder/Review within PI'sinstitution/Reviewwithinmulti-centreresearch group/ Noreview

Date of the Review:

Research Comments of scientific committee/IRC, if any (100 words)

SECTION C: PARTICIPANT RELATED INFORMATION

5.RECRUITMENT AND RESEARCHPARTICIPANTS

a. Type of participants in thestudy:

Healthyvolunteers☐ Patients ☐ Vulnerable persons/ Special groups☐

Others ☐ *(Specify)*

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radioads/ ☐Social Patients/ Family/Friends ☐ Telephone ☐

Others ☐ *(Specify)*

(b) i. Will there be vulnerable persons / special groups involved? Yes ☐ No ☐ NA☐

ii. If yes, type of vulnerable persons / special groups

Children under18yrs ☐ Pregnant orlactatingwomen☐

Differentlyabled(Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized☐ Economically and socially disadvantaged ☐

Refugees/Migrants/Homeless ☐ Terminally ill (stigmatized orrare diseases) ☐

Any other *(Specify)*: ☐

iii. Provide justification for inclusion/exclusion

iv. Are there any additional safeguards to protect researchparticipants?

(c) Is there any reimbursement totheparticipants? Yes ☐ No☐

If yes,Monetary☐ Non-monetary☐ *Providedetails*

d) Are there any incentives to the participants? Yes ☐ No ☐

If yes,Monetary☐ Non-monetary☐ *Providedetails*

e) Arethereanyparticipantrecruitmentfees/incentivesforthestudyprovidedtothePI/Institution?

If yes,Monetary□ Non-monetary□ *Provide details*Yes □ No□

6. BENEFITS ANDRISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risktoparticipants? Yes □ No□

If yes, categorize the level of risk:

Less thanMinimalrisk □ Minimalrisk □

Minor increase over minimal risk or lowrisk □ More than minimal risk orhighrisk□

ii. Describe the risk management strategy:

What are the potential benefits from the study? For theparticipant	Yes	No	If yes,	Direct	Indirect
For the society/community	□	□		□	□
For improvement in science	□	□		□	□
	□	□		□	□

Pleasedescribehowthebenefitsjustifytherisks

Areadverseeventsexpectedinthestudy?Yes □ No□ NA □

a. Arereportingproceduresandmanagementstrategiesdescribedinthestudy? Yes □ No □

b. If Yes, Specify

7.INFORMEDCONSENT

(a) Areyouseekingwaiverofconsent?Ifyes,pleasespecifyreasonsandskiptoitemno.8 Yes □ No□

(b) VersionnumberanddateofParticipantInformationSheet(PIS):

VersionnumberanddateofInformedConsentForm(ICF):

Type of consent planned for:

Signedconsent	□	Verbal/Oralconsent	□	Witnessedconsent	□	Audio-Video(AV) consent	□
ConsentfromLAR (If so, specify fromwhom)	□	Forchildren <7yrs parental/LAR consent	□	Verbalassentfrom minor (7-12 yrs) along with parentalconsent	□	Writtenassentfrommminor (13-18 yrs) along with parentalconsent	□

Other □

(specify)

d) Who will obtain the informedconsent?

PI/Co-I□ Nurse/Counselor □ ResearchStaff □ Other (*Specify)*□

Anytoolstobeused

e) Participant Information Sheet (PIS) and Informed Consent Form(ICF)

English □ Locallanguage □ Other □*(Specify)*

List the languages in which translations were done

Iftranslationhasnotbeendone in local language,pleasejustify

f) Providedetailsofconsentrequirementsforpreviouslystoredsamplesifusedinthestudy[7]

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

Simple language	□	Data/ Sample sharing	□	Compensation for study related injury	□
Risks and discomforts	□	Need to recontact	□	Statement that consent is voluntary	□
Alternatives to participation	□	Confidentiality	□	Commercialization/ Benefit sharing	□
Right to withdraw	□	Storage of samples	□	Statement that study involves research	□
Benefits	□	Return of research results	□	Use of photographs/ Identifying data	□
Purpose and procedure	□	Payment for participation	□	Contact information of PI and Member Secretary of EC	□

Others(Specify) □

8.PAYMENT/COMPENSATION

(a) Whowillbearthecostsrelatedtoparticipationandprocedures?

PI □ Institution □ Sponsor □ Otheragencies □ *(specify)*

(a) Isthereaprovisionforfreetreatmentofresearchrelatedinjuries?Yes □ No□N/A □

Ifyes,thenwhowillprovidethetreatment?

(b) Is there a provision for compensation of researchrelatedSAE?Ifyes,specify.

Yes □ No □N/A □

Sponsor □ Institutional/Corpusfund□ Projectgrant□ Insurance□

(c) Is there any provision for medical treatment or management till the relatedness is determined for injuryto the participantsduringthestudyperiod?Ifyes,specify.Yes □ No□N/A □

(e)Isthereaprovisionforancillarycareforunrelatedillnessduringthestudyperiod?Ifyes,pleasespecify . Yes □ No □ N/A □

9. STORAGE ANDCONFIDENTIALITY

a. Identifying Information: Study Involves samples/data. Yes □ No □ NA □*IfYes, specify* Anonymous/Unidentified □ Anonymized: Reversibly coded □ Irreversibly coded □ Identifiable □ 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)Whowillbemaintainingthedatapertainingtothestudy?

(c)Wherewillthedatabeanalyzedandbywhom?

(d)Forhowlongwillthedatabestored?

(e)Doyouproposetousestoredsamples/datainfuturestudies?Yes □ No □ Maybe □
Ifyes,explainhowyoumightusestoredmaterial/datainthefuture?

SECTION D: OTHER ISSUES

10.PUBLICATION, BENEFIT SHARING AND IPRISSUES

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

b) Willyouinformparticipantsabouttheresultsofthestudy? Yes□No□NA□

c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the studyhasfinished?Ifyesdescribeinbrief(Max50words) Yes □ No □ NA□

d) Isthereanyplanforpostresearchbenefitsharingwithparticipants?Ifyes,*specify* Yes □ No □ NA□

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

f) Doyouhaveanyadditionalinformationtoaddinsupportoftheapplication,whichisnotincluded elsewherein the form? If yes,providedetails.Yes □ No□

SECTION E: DECLARATION AND CHECKLIST

11. 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/WeconfirmthatthisstudywillbeconductedinaccordancewiththelatestICMRNationalEthicalGuidelines forBiomedicalandHealthResearchInvolvingHumanParticipantsandotherapplicableregulationsandguide- lines.
☐	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, New drugs and Clinical Trial Rules 2019 GCP guidelines and other applicable regulations and guidelines.
☐	I/WewillcomplywithallpoliciesandguidelinesoftheinstituteandaffiliatedcollaboratinginstitutionswhereI/Wewillbeconducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC 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 wherever applicable.

Name of PI:

Signature with date:

Name of Co-PI:

Signature with date:

Name of Guide:

Signature with date

Name of HOD:

Signature with date

Administrative requirements

S. No	Items	Yes	No	Enclosure No	IEC remarks
1	Cover letter	☐	☐		
2	Brief CV of all Investigators	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐		
4	Approval of scientific committee	☐	☐		
5	IEC clearance of other centers	☐	☐		
6	Agreement between collaborating partners	☐	☐		
7	MTA between collaborating partners	☐	☐		
8	Insurance policy/certificate	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authoritiesforproposedstudy(whetherinsamelocationorelsewhere) and modification(s) toprotocol	☐	☐		
Proposal related					
12	Copyofthedetailedprotocol[11]	☐	☐		
13	InvestigatorsBrochure(Ifapplicablefordrug/biologicals/devicetrials)	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐		
16	Proforma/Questionnaire/CaseReportForms(CRF)/Interviewguides/ GuidesforFocusedGroupDiscussions(FGDs)(Englishandtranslated)	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐		
Permission from governing authorities					
	Other permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**
18	CTRI	☐	☐	☐	
19	DCGI	☐	☐	☐	
20	HMSC	☐	☐	☐	
21	NAC-SCRT	☐	☐	☐	
22	ICSCR	☐	☐	☐	
23	RCGM	☐	☐	☐	
24	BARC	☐	☐	☐	
25	others (specify)				

Application Form for Exemption from Review

Title of study:

PrincipalInvestigator(Name,DesignationandAffiliation):

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

i. Research on data in the public domain/ systematic reviews ormeta-analyses ☐

ii. Observationofpublicbehavior/informationrecordedwithoutlinkedidentifiersanddisclosure 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. Publichealthprogrammesbygovernmentagencies ☐

vii. Any other (please specify in 100 words):

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

Continuing Review / Annual report format

Title of study:

PrincipalInvestigator(Name,DesignationandAffiliation):

1. Date of IEC approval
2. Validity of approval
3. Date of start of study
4. Proposed date of study completion
5. Period of continuing report from to
6. Does the study involve recruitment of participants Yes □ No □

(a) Ifyes,Totalnumberexpected: NumberScreened: Number Enrolled:.

Number Completed: Number on follow up

(b) Enrolment status – ongoing / completed/stopped

(c) ReportofDSMBYes □ No □ NA

(d) Any other remark

(e) Haveanyparticipantswithdrawnfromthisstudysincethelastapproval? Yes □ No□ NA□

Ifyes,totalnumberwithdrawnandreasons:

7. Isthestudylikelytoextendbeyondthestatedperiod?Yes □ No□

Ifyes,pleaseprovidereasonsfortheextension.

8. Havetherebeenanyamendmentsintheresearchprotocol/InformedConsentDocument(ICD)during thepast approvalperiod?

IfNo,skiptoitemno.9Yes □ No□

(i) Ifyes,dateofapprovalforprotocolandICD:

(II)In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes □ No□

Ifyes,when/how:

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

Ifyes,discussindetail:

10. Have any ethical concerns occurred duringthisperiod?

Yes □ No□

If yes, give details

11. Have any adverse events been noted since thelast review? Yes □ No□

Describe in brief:

12. (a)Have any SAE's occurred sincelastreview?Yes □ No□

If yes, number ofSAE's Type of SAE's:

(b) Is the SAE related tothe study?Yes□ No□

(c) Have you reported the SAE to EC? If no,statereasonsYes □ No□

13. Hastherebeenanyprotocoldeviations/violationsthatoccurredduringthisperiod?

If yes, number of deviations

b) Have you reported the deviations to EC? Yes □ No□

If no,statereasons

14. Incaseofmulticenterictrials, have reportsofoff-siteSAEsbeensubmittedtotheEC?Yes □ No □ NA□

15. Are there any publications or presentations during this period? If yesgivedetails.
Yes □ No□

Any other comments:

Signature of PI:

Application/Notification form for Amendments

1. Title of the study

2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study

6. Details of Amendments

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

7. Impact on Benefit and risk analysis – Yes/No

If yes describe in brief

8. Is anyreconsentnecessary?Yes/No

Ifyes,havenecessarychangesbeenmadeintheinformedconsent? Yes/No

9. Type of review requested foramendment:

Expedited review (No alteration in risktoparticipants) ☐

FullreviewbyEC(Thereisanincreasedalterationintherisktoparticipants) ☐

10. VersionnumberofamendedProtocol/Investigator'sbrochure/ICD:

Signature of PI:

Protocol Violation/Deviation Reporting Form (Reporting by case)

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study
6. Participant ID

7. Total number of deviations /violations reported till date in the study:

8. Deviation/Violation identified by: Principal Investigator/studyteam/ Sponsor/Monitor/SAESubCommittee/EC

9. Isthedeviationrelatedto(Ticktheappropriatebox):

Consenting	☐	Sourcedocumentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participantnon-compliance	☐
Investigational Product	☐	Others*(specify)*	☐
Safety Reporting	☐		

10. Provide details of Deviation/Violation:

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

12. Impact on (if any): Studyparticipant/Quality of data/

13. Areanychangestothestudy/protocolrequired? Yes/No

If yes, give details

14. Signature of PI with date

Serious Adverse Event Reporting Format (Biomedical HealthResearch)

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study

6. Participant details:

Initials/ID
Age at the time of event
Gender : Male/Female
Weight (Kgs) :
Height (cms) :

7. Suspected SAE diagnosis

8. DateofonsetofSAE:

9. Describetheevent

10. Date of reporting SAE

11. Details of suspected intervention causing SAE

12. Report type:Initial/Follow-up/Final

13. If Follow-up report, state date initial report

14. HaveanysimilarSAEoccurredpreviouslyinthisstudy? Yes/NO
Ifyes,pleaseprovidedetails.

15. In caseofamulti-centricstudy,haveanyoftheotherstudysitesreportedsimilar SAEs ?
(Pleaselistnumberofcaseswithdetailsifavailable)

16.

TickwhicheverisapplicablefortheSAE:(KindlynotethatthisreferstotheInterventionbeingevaluatedandNOT diseaseprocess)

A. Expectedevent/ Unexpected event

B. Hospitalization□Increased Hospital Stay □Death □Congenital anomaly/birth defects □

Persistent or significant disability/incapacity□Event requiring intervention (surgical or medical) to prevent SAE□Event which poses threat to life□Others□

17. Incaseofdeath,stateprobablecauseofdeath.

18. No permanent/significantfunctional/cosmetic impairment □
Permanent/significantfunctional/cosmeticimpairment □ NotApplicable □
19.

Describethemedicalmanagementprovidedforadversereaction(ifany)totheresearchparticipant.(In cludeinformationonwhopaid,howmuchwaspaidandtowhom).

20. Provide details of compensation provided / to be provided to participants (Include information on who pays, howmuch, and towhom

21. Outcome ofSAE

Fatal	□	Recovered	□
Continuing	□	Unknown	□
Recovering	□	Other*(specify)*	□

22. Provideanyotherrelevantinformationthatcanfacilitateassessmentofthecasesuchasmedicalhistory

23. ProvidedetailsaboutPI'sfinalassessmentofSAErelatednesstoresearch.

Signature of PI with date

Premature Termination/Suspension/ Discontinuation Report Format

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study
6. Date of last progress report submitted to EC
7. Date oftermination/suspension/discontinuation:
8. Reason for Termination/Suspension/Discontinuation
9. ActiontakenpostTermination/Suspension/Discontinuation(ifany):
10. Plansforpoststudyfollowup/withdrawal(ifany)
11. Details of study participants
    - Total number of participants to be recruited
    - Screened
    - Screen failures
    - Consent with drawn – reason
    - With drawn by PI- reason
    - Active on treatment / Completed treatment/ Participants on follow-up:
    - Participants lost to follow up
    - Number of drop outs
    - Reasons for each drop-out
    - Any other
12. Total number of SAEs reported till date in the study
13. Have any unexpected adverse events or outcomes observed in the study been reported to the EC?**Yes/No**
14. Have there been participant complaints or feedback about the study?**Yes/No**
    If yes provide details
15. Have there been any suggestions from the SAE Sub Committee?**Yes/No**
    If yes have you implemented that suggestion?Yes/No

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

Summary of results:

Signature of PI with date

Application Form for Clinical Trials

1.Title of the study

2. PI details

3. Type of Clinical trial – Regulatory trial / Academic trial

CTRIregistrationnumber:

NABHaccreditationnumber:

ECregistrationnumber

4. IfregulatorytrialprovidestatusofCDSCOpermissionletter

Approved and letterattached/ Applied, under process/ Not applied(Statereason)

5. Tick all categories that apply to yourtrial

Phase-I	☐	PhaseII	☐
PhaseIII	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational Newdrug	☐
Medical devices	☐	New innovativeprocedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalencestudies	☐
Non-drug intervention	☐	Repurposing an existingintervention	☐
Indian system of (AYUSH)medicinePhytopharmaceutical drug	☐	Stemcells	☐
	☐	Approved drug for any newindication ornewrouteofadministration	☐
Others (specify)	☐		

6. Trial design of thestudy

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparisontrial	☐
Cluster	☐	Superioritytrial	☐
Matched-pair	☐	Non-inferioritytrial	☐
Others *(specify)*	☐	Equivalencetrial	☐

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.

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

8. 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:

9. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	□	Clinical and medicalmonitoring	□
Regulatory affairs	□	Datamanagement	□
Statistical support	□	Medicalwriting	□
Site management	□		□

10. 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. Yes □ No □ NA □

If yes, provide details.

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.

11. Describe in brief any preparatory work or site preparedness for the protocol?Yes □ No □ NA □

If yes, provide details

12. Is there an initial screening/use of existing database for participant selection?Yes□ No□ NA□ If Yes, provide details

13. 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.

14. Does the study use a placebo?Yes □ No □ NA □

If yes, justify the use of the placebo and risks entailed to participants.

15. Will current standard of care be provided to the control arm in the study?Yes □ No □ NA □

If no, please justify.

16. Are there any plans to withdraw standard therapy during the study?Yes □ No □ NA □

If yes, please justify

17. Are there any rules to stop the protocol in case of any adverse events?.Yes □ No □ NA □

If yes, please specify

18. Does the study have a Data and Safety Monitoring Plan? Yes □ No □ NA □

If no, please justify.

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

English □ Local language □ Other(Specify) □

(certified that local version (s) is/are a true translation of the English version andcan be easily understood by the participants)

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

18. Is there any insurance coverage of the trial? If yes, provide details. Yes □ No □

19. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?Yes □ No □

Please provide details.

20. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes □ No □

Signature of PI with date

Serious Adverse Event Reporting Format (Clinical trials)

Title of the study

PI details:

Participant details

Initials and Case No
Subject ID
Age at the time of event
Gender: Male/Female
Weight (Kgs)
Height (cms)

2. Report type: Initial □ Follow-up □ Final □

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

4. What was the assessment of relatedness to the trial in the initial report?

By PI – Related □ By Sponsor – Related□ By EC –Related □

Unrelated □ Unrelated □ Unrelated □

5. Describe the event and specify suspected SAE diagnosis

6. Date of onset of SAE: 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:

I. Suspect study drug (include generic name) device/intervention:

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

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

II. Therapy start date: Stop date:

11. Was study intervention discontinued due to event? Yes □ No □

12. Do the reaction decline after stopping or reducing the dosage of the study drug / procedure?

Yes □ No □

If yes, provide details about the reduced dose

13. Did the reaction reappear after reintroducing the study drug / procedure?Yes □ No □ NA □

If yes, provide details about the dose

14. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration:

II. Relevant test/laboratory data with dates:

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

15. Have any similar SAE occurred previously in this study? Yes □ No

If yes, please provide details

16. Seriousness of the SAE:

Death	□	Congenital anomaly	□
Life threatening	□	Required intervention to prevent	
Hospitalization-initial or prolonged	□	permanent impairment / damage	□
Disability	□	Others *(specify)*	□

17. 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).

18. Outcome of SAE:

Fatal	□	Recovered	□
Continuing	□	Unknown	□
Recovering	□	Other *(specify)*	□

19. Was the research participant continued on the trial? Yes □ No □ NA □

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

21. Has this information been communicated to sponsor/CRO/regulatory agencies?Yes □ No □

22. Provide details if communicated (including date)

23.Does this report require any alteration in trial protocol? Yes □ No □

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

Signature of PI with date

Study completion/Final report format

Title of study:

PI (Name, Designation and Affiliation):

Date of EC Approval:

Date of Start of Study:

Date of study completion:

Provide details of

a) Total no. of study participants approved by the EC for recruitment:
b) b) Total no. of study participants recruited:
c) Total number of participants withdrawn from the study (if any):

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

5. Describe the main Ethical issues encountered in the study (if any):

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

7. Describe in brief Plans for archival of records / Record Retention:

8. Is there a plan for post study follow-up –

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

10. Is there a plan for post study benefit sharing with the study participants?

11.Describe results (summary) with Conclusion:

12.Number of SAEs that occurred in the study

13. Have all SAEs been intimated to the EC:

14. Is medical management or compensation for SAE provided to the participants?

INFORMED CONSENTDOCUMENT

Participant information sheet

(i) Statement that the study involves research and explanation of the purpose of the research. In simple language

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the participant or others reasonably expected from research. If no benefit isexpected participants should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the participant.

(vii) Statement describing the extent to which confidentiality of records identifying the participant will bemaintained and who will have access to participant's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomizedtrials).

(ix) Statement describing the financial compensation and the medical management as under:

> (a) In case of an injury occurring to the subject during the clinical trial, free medical management shall begiven as long as required or till such time it is established that the injury is not related to the clinical trial,whichever is earlier.
>
> (b) In the event of a trial related injury or death, the sponsor or his representative or the investigator orcentre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financialcompensation for the injury or death.

(x)An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

(xi) The anticipated prorated payment, if any, to the participant for participating in the trial.

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and thatrefusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeuticeffect.

(xv) Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not haveany therapeutic effect.

(xvi) Any other pertinent information.

Additional elements, which may be required:

(a)Statement of foreseeable circumstances under which the participation of the subject may be terminated by theInvestigator without his or her consent.

(b)Additional costs to the participant that may result from participation in the study.

(c)The consequences of a participant's decision to withdraw from the research and procedures for orderlytermination of participation by Subject.

(d)Statement that the Participant or participant's representative will be notified in a timely manner if significant newfindings develop during the course of the research which may affect the participant's willingness to continueparticipation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo orfoetus, if the participant is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of participants enrolled in the study.

Informed consent form

Study Title:

Study Number:

Participant's Initials: _____ Participant's Name: _____

Date of Birth/Age: _____

Address of the Participant ___

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate) .

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case oftrial related death).

Place Initial box (Subject)

(i) I confirm that I have read and understood the information [ ]

Sheet dated _____ for the above study and havehad the opportunity to ask questions.

(ii) 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.

(iii) I understand that the Sponsor of the clinical trial, othersworking on the Sponsor's behalf, the Ethics Committeeand the regulatory authorities will not need my permissionto look at my health records both in respect of the currentstudy and any further research that may be conducted inrelation to it, even if I withdraw from the trial.I agree to this access. However, I understand thatmy identity will not be revealed in any informationreleased to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arisefrom this study provided such a use is only for scientific purposes [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator’s Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

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 includingMedical 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 Investigatorin 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 conductthe study. I will not begin the study until all necessary ethics committee and regulatory approvals have beenobtained. 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 deviationfrom or changes of the protocol without agreement by the Sponsor and prior review and documented approval orfavourable opinion from the ethics committee of the amendment, except where necessary to eliminate animmediate 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 willensure that the requirements relating to obtaining informed consent and ethics committee review and approvalspecified 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 risksand side effects of the drug.

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

(viii) I agree to maintain adequate and accurate records and to make those records available for audit orinspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, inaccordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with anystudy 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 allunanticipated 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 theethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish thereason for the delay to the satisfaction of the Central Licencing Authority along with the report of the seriousadverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the CentralLicencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial hasbeen 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 andconfidentiality of study data.

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

Signature of Investigator with date.