Shri Shivaji Education Society, Amravati.

Dr. Panjabrao Alias Bhausaheb Deshmukh Memorial Medical College, Amravati.

Institutional Code of Ethics for Research

Dr. Panjabrao Alias Bhausaheb Deshmukh Memorial Medical College,
Panchwati Square, Shivaji Nagar, Amravati- 444603
Website: www.pdmmc.edu.in

Chairperson - Criteria No. _
NAAC Steering Committee
Dr. P. D. M. M. C. Amravati

Dr. P. D. M. Medical College AMRAVATI

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

CONTENT

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmu
Memorial Medical College, Amrava

1.0 Name of Ethics Committee

The Ethics Committee will be called as "Institutional Ethical Committee of Dr. Panjabrao Deshmukh Memorial Medical College, Amravati ". The following may be called as "Standard Operating Procedures for the Institutional Ethical Committee of Dr. Panjabrao Deshmukh Memorial Medical College, Amravati ".

2.0 Abbreviations

Standard Operating Procedures, Institutional Ethical Committee and Dr. Panjabrao Deshmukh Memorial Medical College, Amravati " here in after referred to as SOP, IEC and PDMMC, Amravati respectively.

3.0 Definitions

3.1 SOP

A SOP is an authorized written procedure giving detailed instructions for performing various tasks, OR, SOP is a detailed written instruction to achieve uniformity of the performance of the specific function. This Standard Operating Procedures (SOP) defines the process for writing, reviewing, distributing, and amending SOPs of the IEC, PDMMC, Amravati the SOPs will provide clear, unambiguous instructions to conduct activities of the IEC-PDMMC, Amravati in accordance with the Good Clinical Practices (GCP) guidelines for Clinical Research in India by Central Drugs Standard Control Organization (2001), the ICMR guidelines 2017, New Drugs and Clinical Trial rule 2019, ICMR National Guidelines for Ethics Committees reviewing Biomedical and Health Research during COVI-19 Pandemic, April 2020, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

3.2 Documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, X-rays, and electrocardiograms) that describes or records the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

3.3 Investigator

Investigator is a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator.

3.3.1 Responsibilities of Investigator

- The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as under Section of TABLE 4 given in THIRD SCHEDULE (rules 8, 10, 11, 25, 35, 42 and 49), New Drugs and Clinical Trial Rule 2019 and Chapter IV of Medical Device Rule 2017 and their amendments time to time.
- Its Investigator responsibility to strictly follow these rules
- Investigator shall conduct any clinical investigation in respect of investigational medical device in human participants in accordance with these rules and with the permission granted by the Central Licensing Authority. Grant of permission to conduct clinical investigation on medical device to be obtained by Investigator from Central Licensing Authority in Form MD-22 to be obtained by Investigator or sponsor. Grant of permission to conduct, clinical performance evaluation of new in vitro diagnostic medical device shall be made to the Central Licensing Authority in Form MD-24 to need to be obtained by Investigator or sponsor.
- Investigator should submit undertaking. New Drugs and Clinical Trial Rule 2019, G.S.R. 227(A), dated 19th March 2019 and Table 9 (Annexure 01), G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017 for conduct of clinical trial and clinical investigation on medical device.
- Investigator should prepare and submit case record form as per Table 6 (Annexure 02), G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017 for conduct clinical investigation on medical device to Ethics Committee for approval.
- Standard operating procedures are required to be documented by the investigators for the tasks performed by them.
- During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.
- Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the Investigator as well as sponsor to chairman of the ethics committee, Head of the Institution where the trial has been conducted and licensing authority in a format of Table 5 (Annexure 03) THIRD SCHEDULE (rules 8, 10, 11, 25, 35, 42 and 49), New Drugs and Clinical Trial Rule 2019 and Table 7 (Annexure 04), (G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017) within fourteen (14) days of occurrence of serious adverse event of death.
- The report of the serious adverse event other than death, after due analysis, shall be

forwarded by the Investigator to the Licensing authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen(14) days of occurrence of the serious adverse event. (in a format of Table 5 (Annexure 03) THIRD SCHEDULE (rules 8, 10, 11 , 25, 35, 42 and 49), New Drugs and Clinical Trial Rule 2019 and Table 7 (Annexure 04), G.S.R. 78(E), Medical Device Rule 2017, dated 3 1st January 2017 within fourteen (14) days of occurrence of serious adverse event.

- In case, the Investigator fails to report any serious adverse event within the stipulated period, he/she shall have to furnish the reason for the same to the satisfaction of the Licensing Authority along with the report of the serious adverse event" (New Drugs and Clinical Trial Rule 2019, G.S.R.227 (E), dated 19th March 2019 and Medical Device Rule 2017, dated 31st January 2017).
- The investigator shall provide information to the clinical trial subject through informed consent process as provided in TABLE 3 (Annexure 05) of New Drugs and Clinical Trial Rule 2019aboutthe essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death and as per Table 8 (Annexure 06), (G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017) in case of medical device related studies.
- The investigator shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.
- An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of
- providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record".

3.4 Co-investigator(s)

Co-investigator(s) is/are a person(s) legally qualified to be an investigator, to whom the Investigator delegates a part of his responsibilities.

3.5 Sponsor

Sponsor is an individual or a company or an institution that takes the responsibility for the initiation, management and / or financing of a Clinical Study. An Investigator who independently initiates and takes full responsibility for a trial automatically assumes the role of a Sponsor.

3.5.1 Responsibilities of Sponsor

- The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.
- Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.
- In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within three (3) months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 07), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;
- Clinical investigation of medical device and clinical performance evaluation of new in vitro diagnostic medical device will be carried out as per CHAPTER VII of Medical Device Rule 2017 and its amendments time to time. Sponsor shall conduct any clinical investigation in respect of investigational medical device in human participants except in accordance with these rules and in accordance with the permission granted by the Central Licensing Authority. Grant of permission to conduct clinical investigation on medical device to be obtained by sponsor from Central Licensing Authority in Form MD-22 to be obtained by sponsor. Grant of permission to conduct, clinical performance evaluation of new in vitro diagnostic medical device shall be made to the Central Licensing Authority in Form MD-24 to be obtained by sponsor.
- Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee, Head of the Institution where the trial has been conducted and licensing authority in a format of Table

- 5(Annexure 03) THIRD SCHEDULE (rules 8, 10, 11, 25, 35, 42 and 49), New Drugs and Clinical Trial Rule 2019 and Table 7 (Annexure 04), G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017within fourteen(14) days of occurrence of serious adverse event of death.
- The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen(14) days of occurrence of the serious adverse event. (in a format of Table 5 (Annexure 03) THIRD SCHEDULE (rules 8, 10, 11, 25, 35, 42 and 49), New Drugs and Clinical Trial Rule 2019 and Table 7 (Annexure 04), G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017 within fourteen (14) days of occurrence of serious adverse event.
- In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as New Drugs and Clinical Trial Rule 2019, G.S.R. 227(E), dated 19th March 2019. The sponsor or his representative, whosoever had obtained permission from the Licensing Authority for the conduct of clinical trial, shall pay the compensation within thirty (30) days of the receipt of such order in case of clinical trial related injury or death as per the order of Licensing Authority as defined under CHAPTER VI, COMPENSATION (New Drugs and Clinical Trial Rule 2019, G.S.R.227 (E), dated 19th March 2019).

4.0 Objective of SOP of IEC-PDMMC, Amravati.

The objective of this SOP is to maintain effective functioning of IEC-PDMMC, Amravati and to ensure the quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human subjects.

5.0 Responsibility of IEC- PDMMC, Amravati

The responsibility of IEC- PDMMC, Amravati will be to ensure that the research projects that are carried out at Dr. Panjabrao Deshmukh Memorial Medical College, Amravati

DEAN
Dr. Panjabrao Alias Bhausaheb Deshm
Memorial Medical College, Amravat

1) Are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on Harmonization/Good Clinical Practice guidelines.
2) Do not compromise right, safety and benefits of the patients or volunteers/ study participants.
3) Are conducted under the supervision of trained medical / bio-medical persons with the required expertise.
4) Include, solely, patients or participant who has given voluntary and informed consent.

The IEC-PDMMC, Amravati will also ensure that no research project shall be / can be started unless Ethics Clearance /Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor vetted by the Institutional Ethical Committee.

6.0 Functions of IEC-PDMMC, Amravati.

- To provide independent, competent and timely review of the ethical aspects of the proposed studies before their commencement and monitoring the ongoing studies regularly.
- To review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.
- To review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example periodic reports, final reports and site visits etc.
- To review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects.
- To look into the aspects of informed consent process, risk-benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.
- To ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence; Non-malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research.
- To examine compliance with all regulatory requirements, applicable guidelines and laws.
- To record the reasons for revoking of its approval accorded to a trial protocol, and to communicate such a decision to the Investigator as well as to the Licensing Authority.
- To forward the report, in case of serious adverse event of death occurring to the clinical trial

subject, after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21 (b) for conducting the clinical trial, to the Licensing Authority within thirty (30) days of the occurrence of the serious adverse event of death as per New Drugs and Clinical Trial Rule 2019,G.S.R.

- 227(A), dated 19th March 2019 and Medical Device Rule 2017, dated 31st January 2017 in case of death related to medical device.
- To forward the report, in case of serious adverse event, other than death occurring to the clinical trial subject, after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21 (b) for conducting the clinical trial, to the Licensing Authority within thirty (30) days of the occurrence of the serious adverse event of death as per New Drugs and Clinical Trial Rule 2019,G.S.R. 227(A), dated 19th March 2019 and Medical Device Rule 2017, dated 31st January 2017.

7.0 Composition of IEC-PDMMC, Amravati.

The IEC-PDMMC, Amravati will comprise of 7-15 members for smooth functioning of Institutional Ethical Committee as too many members will hinder the decision making by delay to arrive at consensus. The Chairman of the committee will be from outside the

Institution and not Head/former Head the institute to maintain the independence of the committee. The Member Secretary, drawn from the institution itself, will conduct the business of the Committee. Other members will be from medical and non-medical, scientific and non-scientific background including a representative from the general public to reflect the differed viewpoints. There will be adequate representation of age and gender in the committee to safeguard the interests and welfare of all sections of the society.

The IEC-PDMMC, Amravati will include:

1. The Chairman
2. One — two Medical Scientists (One Pharmacologist is compulsory)
3. One — two Clinicians
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary agency
6. One philosopher/ ethicist/ theologian
7. One lay person from the community
8. Member Secretary

IEC-PDMMC, Amravati will have a set of 5-6 alternate members which will be referred as 'Additional Members' who can be invited as members with decision making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

IEC-PDMMC, Amravati will have sub committees such as the scientific review committee and Board of research studies (BORS) committee. These will be part of the main committee and comprise Chairperson/Member Secretary and two - three appropriate designated members of the main IEC-PDMMC, Amravati as defined in the SOPs.

7.1 Procedure for constitution of IEC-PDMMC, Amravati.

1. Dean, PDMMC, Amravati will select and nominate the Chairman and Member Secretary for IEC-PDMMC, Amravati.
2. The IEC will be constituted by the Dean in consultation with the Chairman.
3. The Dean, PDMMC, Amravati will invite the members to join ethics committee by sending the official request letter (Annexure 08).
4. Members will confirm their acceptance to the Dean, PDMMC, Amravati by providing all the required information for membership (Annexure 09)
5. The Dean, PDMMC, Amravati will offer formal appointment orders to the members of IEC after the receipt of their acceptance and signing the agreement of confidentiality.
6. The Dean, PDMMC, Amravati will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve (Annexure 10).
7. The Dean, PDMMC, Amravati will designate and instruct Chairman of IEC or his representative to conduct the regular proceedings of the IEC for the institute.
8. At regular intervals, the Dean, PDMMC, Amravati will review the functioning of IEC.

8.0 Membership requirement

1. The duration of appointment of members will be initially for ***a period of five (05) years***.
2. At the end of five (5) years, the committee will be reconstituted for reregistration and 50% members will be replaced by new members with a defined procedure.
3. Member should be aware of local, social and cultural norms, as this is an important social control mechanism.
4. Members should be conversant with the provisions of clinical trials under New Drugs and Clinical Trial Rule 2019, G.S.R. 227(A), dated 19th March 2019, Medical Device

Rule 2017, dated 31st January 2017,1CMR National Guidelines for Ethics Committees reviewing Biomedical and Health Research during COVI-19 Pandemic, April 2020 and Good Clinical Practice (GCP) guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects and update in these guidelines time to time.

5. The members representing as basic medical scientists and clinicians should have post-graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

8.1: Confidentiality and conflict of interest:

- It is the responsibility of each IEC member reviewing research project or attending IEC meeting to read, understand, accept and sign the agreement contained in the confidentiality / conflict of interest form. (Annexure No. 11 to Annexure No. 14)
- The form should be read, understood, accepted and signed by each IEC member at the beginning of the tenure of his/ her membership and before he or she starts reviewing the research proposals.
- Any guest or observer/ independent consultant attending an IEC meeting will also read, understand accept and sign the confidentiality/ conflict of interest form before attending the IEC meeting or ethical review process.
- The forms which duly signed and dated will be kept for record purpose in a separate file entitled "Confidentiality / Conflict of Interest agreement form in the IEC office.
- There should be no conflict of interest. If there is any conflict of interest then the member should declare it in written to the chairman prior to review. The member shall voluntarily withdraw from the ethics committee meeting while decision is being taken and this will be recorded in minutes of the meeting.
- In case one of the ethics committee members is part of the research team either as a Principal investigator or Co- investigator, then the member shall not participate in the discussion.

9.0 Terms of references (TORs)

1. The Terms of References include working of IEC with regards to its members and will be maintained in IEC-PDMMC, Amravati office. This will include

a) Terms of appointment of the members with reference to the duration of their term, the policy for their removal, replacement and resignation,

b) Frequency of the meetings

c) Payment of processing fee to the IEC for review

d) Honorarium / consultancy to the members/consultants

2. As per the changing requirements of the committee, the SOP will be updated periodically. The term of appointment of members could be extended for another term on the basis of his/her contribution and a defined percentage of members could be changed on regular basis. Persons either trained in bioethics or well conversant with ethical guidelines and laws of the country would be preferred. Substitute member may be nominated if meetings have been continuously missed by a member due to any unforeseen circumstances.

10.0 Quorum requirement

Minimum of 50% committee strength plus one member and not less than five (05) members will be required to compose a quorum.

A quorum should include at least one member whose primary expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/research site. No quorum should consist entirely of members of one profession or one gender.

The quorum requirements of IEC-PDMMC, Amravati will have the following representation:

1. Basic medical scientists (preferably a pharmacologist)
2. Clinicians
3. Legal expert
4. Social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
5. Lay person from the community

11.0 Procedure for resignation, replacement or termination of members

11.1 Resignation/replacement procedure

1. A member can tender resignation from the committee with proper reasons to do so.
2. In case of inability to attend the meeting, members are contacted either personally or telephonically and if they wish to rescue themselves, they are allowed to do the same with prior permission of the Chairman/ member secretary.
3. The members who have resigned may be replaced at the discretion of the Director, PDMMC, Amravati in consultation with Chairman, IEC.

4. IEC members who decide to withdraw must provide Chairman/ Member Secretary, the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.
5. In case of resignation, the Dean will appoint a new member in consultation with the Chairman, falling in the same category of membership ex. Basic Medical Scientist with Basic Medical Scientist. Recommendations may be sought from the resigning member.
6. Appointment may be made with joint consultation of the Member Secretary and the Chairman.
7. In case of new appointment of a member, the procedure as described in section 7.1 Procedure for constitution of IEC-PDMMC, Amravati will be adopted.

11.2 Termination procedure

- The membership will be reviewed by the IEC if the contribution of the member is not adequate and/or there is long period of (member) non availability
- In all such situations/circumstances, Dean in consultation with Chairman/Member Secretary can serve a letter of termination to the member.
- Documentation of the termination will be recorded in the minutes of the next duly constituted IEC meeting and IEC membership circular will be revised.

12.0 Conduct of IEC meetings

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

13.0 Independent consultants

IEC-PDMMC, Amravati may call upon subject experts as independent consultants who may provide special review of selected research protocols, if needed.

IEC-PDMMC, Amravati may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the IEC PDMMC, Amravati or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.(ICMR National Ethical

Guidelines 2017). If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, will be included, pediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights in the decision-making process which will be made by the members of the IEC-PDMMC, Amravati. (ICMR National Ethical Guidelines 2017).

14.0 Application procedure

1) All proposals should be submitted in the prescribed application form, on any of the working day.
2) To consider proposals in the forthcoming meeting, the proposals should be submitted three weeks in advance of scheduled meeting. The proposals submitted after this period will be considered in next meeting.
3) All the research proposals must be submitted in English language only.
4) The applicant of proposal should submit three (03) hard copies and one soft copy by email/online portal of proposal along with relevant documents.
5) Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators /Collaborators should be forwarded by the Head of the Departments and Institution to the ethical committee.
6) All proposals should be submitted for IEC review only after the approval of ***Scientific Review committee and BORS committee.*** Proof of approval needs to be submitted.
7) The application should be addressed to the Chairman, Institutional Ethical Committee, Dr. Panjabrao Deshmukh Memorial Medical College, Amravati through Member Secretary.
8) IEC office will verify the proposals for completeness, as per the checklist (Form 5: Annexure- 15).
9) Receipt of the application will be acknowledged by the IEC office.
10) The date of meeting will be intimated to the Principal Investigator, to be present, if necessary to offer clarifications. The Principal Investigator should prepare brief presentation of his/her research proposal. If required, he/she may be asked to present in IEC meeting to clarify the points raised by the members.
11) The Principal Investigator and preferably the members from of his/her research team should be present for the meeting to offer clarifications, if necessary.

12) The decision of IEC regarding the proposal will be communicated to the Principal Investigator in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

15.0 Processing fee

1. The waiver of processing fee is permissible to all the research proposals which are non-funded studies and departmental studies.
2. Projects/studies funded by government agencies like ICMR, UGC, DST Government of India, State Science & Technology Department and other non-profitable funding agencies like UNICEF, WHO, USAID etc. will be levied 5% processing charges of total budge of project /study for PDMMC, Amravati.
3. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies. Agencies, Multinationals will be levied 10 % processing charges of total budget of project /study for PDMMC, Amravati.
4. Processing fees will be handled as per Institutional Protocol.

16.0 Documentation

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted
3. Approval of the Head of the Department and Institution
4. Protocol of the proposed research mentioning the approximate duration for which it will be conducted.
5. Ethical issues in the study and plans to address these issues.
6. All relevant annexure like Proforma, Case Report Forms, questionnaires, follow - up cards, etc. (Annexure No.16 to Annexure No.01, Annexure 17, Annexure 24)
7. Informed consent process, including patient information sheet and written informed consent form in English and local language(s). The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per New Drugs and Clinical Trial Rule 2019 and Medical Device Rule 2017.
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from

DEAN
Dr. Panjabrao Alias Bhausaheb
Memorial Medical College

9. other centres within the country / countries, if available.
10. Curriculum vitae of all the investigators with relevant publications in last five years.
11. Any regulatory clearances required.
12. Source of funding and financial requirements for the project.
13. Other financial issues including those related to insurance.
14. An agreement to report only Serious Adverse Events (SAE) to IEC (Annexure 03, Annexure 04)
15. Statement of conflicts of interest, if any.
16. Agreement to comply with the relevant national and applicable international guidelines.
17. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable.
18. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECS or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
19. Plans for publication of results — positive or negative- while maintaining the privacy and confidentiality of the study participants.
20. Any other information relevant to the study
21. An agreement to submit periodic progress report and final report at the end

17.0 Review procedure for research proposal

17. 1 Review Procedure

1. The meeting of IEC-PDMMC, Amravati will be held on periodic interval i.e. ***every six months***. Additional meetings will be held as and when necessary in accordance with the workload.
2. The proposals must be sent to the IEC-PDMMC, Amravati at least three (03) weeks in advance of scheduled meeting.
3. The IEC's member-secretary or secretariat will screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review.
4. The decisions will be taken by consensus after discussion in the meeting and not by circulation of the proposal. The decision of Chairman will be final.

5. Researchers will be invited to offer clarifications if need be. If required, the Principal Investigator will be asked to present the research proposal. In absentia of principal investigator (with prior permission), co-investigator will be asked to present the research proposal.
6. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed. The decisions will be documented in the minutes and Chairman's approval will be taken in writing.

17. 2 Types of review

17.2.1 Exemption from review

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

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

Exceptions:

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

17.2.2 Expedited review

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

- Minor deviations from originally approved research during the period of approval (usually of one year duration).
- 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.
- Research activities that involve only procedures listed in one or more of the following categories:

1. Clinical studies of drugs and medical devices only when

i. research is on already approved drugs except when studying drug interaction or

conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

- 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.

a. Research on interventions in emergency situation

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

1. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
2. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
3. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
4. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be

periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

1. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
2. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
3. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
4. Protection must be ensured so that only minimal additional risk is imposed.
5. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.
6. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
7. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

c. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

17.2.3 Full review

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

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

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;

iii. From neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 — 72 hours. If more than

this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by non-invasive means. For instance:

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

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

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

ii. Weighing or testing sensory acuity;

iii. Magnetic resonance imaging;

iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow.

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

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

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

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

18.0 Review procedure for research proposal involving vulnerable population

1. Vulnerable research participants are individuals whose willingness to volunteer in a research trial may be duly influenced by the expectation (whether justified or not), benefits associated with participation, retaliatory response from higher authority in case of refusal to participate, and whose consent may not be valid for various reasons. They include infants, children and adolescents, pregnant and lactating women, students and employees, mentally challenged patients, critically ill patients etc.
2. All the IEC members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
3. Vulnerable group can become participants only if the study is designed to protect or advance the health of this population and for which the nonvulnerable group would not be suitable participants
4. In case of trials involving children, the assent of the child should be obtained from the age of twelve to eighteen (12-18) years unless there is no medically accepted alternative to the therapy (provided consent has been obtained from parents/guardian) (Annexure 20).
5. The language and presentation of the contents in the 'Participant Information Sheets' and the 'Consent/Assent forms' must be in the manner which is understood by a child of 10 years of age (that is, to a fifth grade level)
6. For the adult participants who are unable to provide consent for themselves, only their legal guardian can sign the consent form on their behalf. The legal relationship must be confirmed by the primary investigator (research team) and the necessary evidence (documents) must be viewed and recorded.
7. Rights and welfare of people who are unable to give informed consent must be protected. Informed consent should be obtained from legally accepted representatives (LAR) in the presence of impartial witness with adequate explanation of risks and

benefits. Expert opinion of additional members would be obtained if necessary.

8. Expert opinion of additional members would be obtained if necessary.

19.0 Elements of review

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

21.0 Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary in writing only to the Principal Investigator within 10 working days after the meeting at which the decision was taken in the specified format (Annexure 26). A certificate of approval will be sent to the applicant within 15 working days (Annexure 27). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.
2. Suggestions for modifications, if any, will be sent by IEC-PDMMC, Amravati.
3. Reasons for rejection will be informed to the researchers.

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

22.0 Follow-up procedure of approved proposals

1. Progress reports should be submitted at prescribed intervals for review and final report should be submitted at the end of study (Annexure 25).
2. IEC-PDMMC, Amravati will review progress of all the studies, from the time of decision till termination of study, for which positive decision has been taken by IEC.
3. The progress of all the research proposals will be followed at a regular interval of at least once-a-year. However, in special situations, IEC will conduct the follow-up review at shorter intervals in accordance with the need, nature and events of research project.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any new information related to the study should be communicated in writing to IEC-PDMMC, Amravati.
6. The following events should be reported as "Serious Adverse Events" by the investigators.
   a. The death of a study subject, whether or not related to an investigational agent.
   b. A life-threatening adverse event.
   c. Inpatient hospitalization or prolongation of existing hospitalization for more than 24 hours (excluding elective hospitalization for conditions unrelated to the study)
   d. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
   e. A birth defect in an offspring of a study participant, regardless of the time after the study, the congenital defects is diagnosed.
7. A decision of a follow-up review will be issued and communicated to the applicant indicating modification/suspension/termination/continuation of the project.
8. Premature termination of study should be notified to IEC-PDMMC, Amravati with reasons along with summary of the data obtained so far.
9. Change of investigators / sites should be informed to IEC-PDMMC, Amravati.

23.0 Record keeping and archiving

1. The documents will be properly dated, filed, labelled and archived in secure place in IEC-PDMMC, Amravati office cabinet for future reference.
2. IEC-PDMMC, Amravati will keep record of following documents.
   a. Constitution and composition of IEC-PDMMC, Amravati.

b. Standard Operating Procedures of IEC-PDMMC, Amravati.

c. Curriculum Vitae (CV) of all members of IEC.

d. The published guidelines established by IEC-PDMMC, Amravati. for submission of research proposal.

e. Copy of all study protocols with enclosed documents, progress reports, and SAEs.

f. Agendas and minutes of all IEC meetings duly signed by the Chairman.

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

h. Copy of all correspondence with members, researchers and other regulatory bodies.

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

j. Final report of the approved projects.

k. Record of all income and expenses of the IEC, including allowances and reimbursements made to the secretariat and EC members;

3. All documents related to research proposal will be archived for a minimum period of five years (05 years) after the completion/termination of study.
4. One soft of copy of research proposals will be archived and rest of the copies will be destroyed after one year.
5. Only authorized person will have access to data related to IEC-PDMMC, Amravati.

24.0 Updating IEC-PDMMC, Amravati members

1. All relevant new guidelines should be brought to the attention of IEC members.
2. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism.
3. The IEC members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.
4. For drug trial review, it is preferable to train the IEC members in Good Clinical Practice.

DEAN
Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

DEAN
Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Annexure – I

Undertaking by the Investigator for Medical Device Study

(Table 09: Medical Device Rule 2017, dated 31't January 2017)

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)

2. Name and address of the medical college, hospital or other facility where the Clinical Investigation will be conducted: Education, training & experience that qualify the Investigator for the clinical investigation (Attach details including medical council registration number, or any other statement(s) of qualification(s))

3. Name and address of all clinical facilities to be used in the clinical investigation.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the clinical investigation.

5. Names of the other members of the research team (Co-Investigators or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).

6. Clinical Investigation Plan, Title and Clinical investigation number (if any) of the clinical investigation to be conducted by the Investigator.

7. Commitments:

(i) I have reviewed the clinical investigation plan and agree that it contains all the necessary information to conduct the investigation. I will not begin the clinical investigation until all necessary Ethics Committee and regulatory approvals have been obtained.

(ii) I agree to conduct the investigation in accordance with the current Clinical investigation plan. I will not implement any deviation from or changes of the Clinical investigation plan without agreement by the Sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the clinical investigation participant or when the change(s) involved are only logistical or administrative in nature.

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

(iv) I agree to inform all Subjects that the medical devices are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and Ethics Committee review and approval specified in this Schedule 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 and Good Clinical practice guidelines.

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

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

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

(viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and provisions of these rules. I will fully cooperate with any clinical investigation related audit conducted by regulatory officials or authorized representatives of the Sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the CIP activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all serious adverse events to the Sponsor, Central Licensing Authority as well as the Ethics Committee within forty-eight hours of their occuffence. In case of failure, I will submit the justification to the satisfaction of the Central Licensing Authority. I also agree to report the serious adverse events, after due analysis, to the Central Licensing Authority, Chairman of the Ethics Committee and head of the institution where the investigation has been conducted within fourteen days ofthe occurrence ofserious adverse events.

(xi) I will maintain confidentiality of the identification of all participating clinical investigation patients and assure security and confidentiality of clinical investigation data.

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

Date: **Signature of Investigator**

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Case Report Form (CRF) For Investigational Medical Device

(Table 06: G.S.R. 78(E), Medical Device Rule 2017, dated 31't January 2017)

1. General

(i) Case Report Forms are established to implement the clinical investigation plan, to facilitate subject observation and to record subject and investigational medical device data during the clinical investigation according to the clinical investigation plan. They can exist as printed, optical, or electronic documents and can be organized into a separate section for each subject.

(ii) The Case Report Forms should reflect the clinical investigation plan and take account of the nature of the investigational medical device.

2. Content and format

2.1 Overall considerations

(i) The Case Report Forms can be organized such that they reflect all the data from a single procedure or a single visit or other grouping that makes clinical or chronological sense.

(ii) The format of Case Report Forms shall be such as to minimize errors that can be made by those who enter data and those who transcribe the data into other systems.

(iii) The data categories and format listed in this Table can be considered when designing a Case Report Form.

2.2 Cover page or login screen

(1) Name of sponsor or sponsor logo.

(2) Clinical investigation plan version and date (if required).

(3) Version number of Case Report Forms.

(4) Name of clinical investigation or reference number (if applicable).

2.3 Header or footer or Case Report Form identifier

(a) Name of the clinical investigation or reference number.

(b) Version number of Case Report Forms.

(c) Investigation site/principal investigator identification number.

(d) Subject identification number and additional identification such as date of birth or initials, if allowed by national regulations.

(e) Case Report Form number or date of visit or visit number.

(f) Page/screen number of CRF and total number of pages/screens (e.9. "page x of xx").

2.4 Types of Case Report Forms

The following is a suggested list of CRFs that may be developed to support a clinical investigation. This is not an exhaustive list and is intended to be used as a guideline.

(a) Screening.

(b) Documentation of subject's informed consent.

(c) Inclusion/exclusion.

(d) Baseline visit:

(1) Demographics;

(2) Medical diagnosis;

(3) Relevant previous medications or procedures;

(4) date of enrolment;

(5) Other characteristics.

(e) Intervention(s) or treatment(s).

(f) Follow-up visit(s).

(g) Clinical investigation procedure(s).

(h) Adverse event(s).

(i) Device deficiencies.

(j)Concomitant illness(es)/medication(s).

(k) Unscheduled visit(s).

(l) Subject diary.

(m) Subject withdrawal or lost to follow-up.

(n) Form signifying the end of the clinical investigation, signed by the principal investigator or his/her authorized designee.

(o) CIP deviation(s).

3. Procedural issues

A system shall be established to enable cross-referencing of CRFs and CIP versions. Supplemental CRFs may be developed for collecting additional data at individual investigation sites in multicenter investigations.

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

(Table 05: New Drugs and Clinical Trial Rule 2019, dated 19th March 2019)

1. Patient Details:

Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc.)*

Gender

Age or date of birth

Weight

Height

2. Suspected Drug(s) :

Generic name of the drug*

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

Dosage form and strength.

Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).

Route of administration.

Starting date and time of day.

Stopping date and time, or duration of treatment

3. Other Treatment(s):

Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Serious Adverse Event :

Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*

Start date (and time) of onset of event.

Stop date (and time) or duration of event.

Dechallenge and rechallenge information.

Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator*

Name and Address Telephone number

Profession (specialty)

Date of reporting the event to Central Licencing Authority:

Date of reporting the event to ethics committee overseeing the site:

Signature of the Investigator or Sponsor

Note: Information marked * must be provided.

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A MEDICAL DEVICE CLINICAL INVESTIGATION

(Table 07: Medical Device Rule 2017, dated 31st January 2017)

1. Patient details:

a) Initials and other relevant identifier (hospital/Out Patient Department's record number etc.);

b) Gender;

c) Age and date of birth;

d) Weight;

e) Height.

2. Suspected device(s):

a) Name of the Device;

b) Indication(s) for which suspect device was prescribed;

c) Device details including model number/size/lot number, if applicable;

d) Starting date and time of day;

e) Stopping date and time, or duration of treatment;

3. Other treatment(s):

Provide the same information for concomitant treatment.

4. Details of suspected adverse device reaction(s)

a) Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.

b) Start date (and time) of onset of reaction.

c) Stop date (and time) or duration of reaction.

d) Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome

a) Information on recovery and any sequel; results of specific tests and/or treatment that may have been conducted.

b) For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.

c) Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator:

a) Name;

b) Address;

c) Telephone number;

d) Profession (specialty);

e) Date of reporting the event to Central Licensing Authority;

f) Date of reporting the event to Ethics Committee overseeing the site;

g) Signature of the Investigator.

Informed Consent Document For Drug Clinical Trial

(Table 03: New Drugs and Clinical Trial Rule 2019, dated Lgth March 2019)

1. Checklist of informed consent documents for clinical trial subject:

1.1 Essential elements:

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

(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 Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

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

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

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

(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 be given 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 ofa trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation 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 subject 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 that refusal 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 therapeutic effect.

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

(xvi) Any other pertinent information.

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College Amravati

1.2 Additional elements, which may be required:

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

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

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

(d) (d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

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

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

2. Format of informed consent form for Subjects participating in a clinical trial

–

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject: _____

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 of trial related death).

Place Initial box (Subject)

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

Sheet dated _____ for the above study and have had 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, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be

conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

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

Name of the Witness: _____ Date: _____/_____/_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Informed Consent Document for Medical Device Clinical Investigation

(Table 08: G.S.R. 78(E), Medical Device Rule 2017, dated 31't January 2017)

Checklist for clinical investigation Subject's informed consent documents

1.1 Essential elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to Subject's medical records
8. Clinical investigation treatment schedule(s) and the probability for random assignment to each treatment (for randomised clinical investigation)
9. Statement describing the financial compensation and medical management as under:

(a) In case of an injury occurring to the subject during the clinical investigation, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical investigation, whichever is earlier.

(b) In the event of an investigation related injury or death, the Sponsor or his representative, whoever has obtained permission from the Central Licensing Authority for conduct of the clinical investigation, shall provide financial compensation for the injury or death.

10. An explanation about whom to contact for clinical investigation related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the clinical investigation
12. Subject's responsibilities on participation in the clinical investigation
13. Statement that participation is voluntary, that the Subject can withdraw from the clinical investigation at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Statement that there is a possibility of failure of investigational medical device to provide intended therapeutic effect.
15. Any other pertinent information.

1.2 Additional elements, which may be required

(a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.

(b) Additional costs to the Subject that may result from participation in the clinical investigation.

(c) The consequences of a Subject's decision to withdraw from the investigation and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings are developed during the course of the investigation which may affect the Subject's willingness to continue participation will be provided.

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

(f) Approximate number of Subjects enrolled in the clinical investigation

2. Format of informed consent form for Subjects participating in a clinical investigation

Informed Consent form to participate in a clinical investigation

Clinical investigation Title:

Clinical investigation Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth / Age: _____Gender: _____

Address of the Subject: _____

Qualification: _____

Occupation: Student/Self-employed/Service/Housewife/Others (Please tick as appropriate)

Annual income of the subject: _____

Name and address of the nominee(s) and his relation to the subject _____

(for the purpose of compensation in case of clinical investigation related death).

Place initial box (Subject)

(i) I confirm that I have read and understood the information sheet dated for the above clinical investigation and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the clinical investigation 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 investigation, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current clinical investigation and any further research that may be conducted in relation to it, even if I withdraw from the clinical investigation. I agree

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

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

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

(vi) I understand that in case of an injury occurring during the clinical investigation, free medical management shall be given as long as required.

(vii) I understand that in the event of an investigation related injury or death, financial compensation for such injury or death shall be provided in accordance with the provisions of the Medical Device Rules, 2017.

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

Date: ____/____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Contact Details (Telephone Number/ mobile) on which subject may contact: _____

Date: ____/____/_____

Clinical investigation Investigator's Name: _____

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

Name of the Witness: _____

Address and contact details of the Witness: _____

(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant).

Ongoing Approved Research Review Submission Form (Form 4A)

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

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

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Annexure – 8

Constitution of Institute Ethics Committee of Dr. PDMMC, Amravati.

Letter Ref. No. Date:

From
Dean
Dr. PDMMC, Amravati.

To
_____
_____
_____

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

Dear Sir/ Madam,

On behalf of Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, I request your concurrence for appointment as a Chairman/Member of Institute Ethics Committee of Dr. PDMMC, Amravati.

Kindly send your written acceptance in the enclosed format. You are also requested to provide your brief *curriculum vitae*.

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

Thanking you

Yours sincerely,

Name and Signature of Director, Dr. PDMMC, Amravati.

Annexure – 9

Consent letter to be Chairman/Member of IEC-Dr. PDMMC, Amravati

From,

_____

_____

_____

To
The Dean
Dr. Panjabrao Deshmukh Memorial Medical College, Amravati.

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

Ref: Your Letter No: dated:

Dear Sir,

In response to your letter stated above, I give my consent to become Chairman/Member of Institute Ethics Committee (IEC) of Dr. PDMMC, Amravati.. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

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

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

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

I herewith enclose my curriculum vitae.

Thanking you,

Yours sincerely,

Signature.....

Name of the Chairman/Member ---------- Date:

Address:

Telephone No: Mobile: Office: Residence:

Email:

DEAN
Dr. Panjabrao Alias Babasaheb Deshmukh
Memorial Medical College, Amravati

Office order of constitution of IEC-Dr. PDMMC, Amravati

Letter Ref. No.: Date:

OFFICE ORDER

I herewith establish and constitute an Ethics Committee of Dr. Panjabrao Deshmukh Memorial Medical College, Amravati, to ensure a competent review of all ethical aspects of project proposal received and execute the same free from any bias and influence that could affect the objective.

The following members will constitute the Institute Ethics Committee (Human studies)

1. Chairman_____
   Designation_____ Affiliation
2. Member Secretary(Convener)
   Designation_____ Affiliation
3. Member
   Designation_____ Affiliation
4. Member
   Designation_____ Affiliation
5. Member
   Designation_____ Affiliation
6. Member
   Designation_____ Affiliation
7. Member
   Designation_____ Affiliation
8. Member
   Designation_____ Affiliation
9. Member
   Designation_____ Affiliation
10. Member
    Designation_____ Affiliation

The tenure of this membership will be for a period of 2 years extendable to 3 years from the date of appointment.

Signature
Dean, Dr. PDMMC, Amravati.

Confidentiality Agreement Form for IEC Members

In recognition of the fact, that I _____

_____

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

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

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well- being of research participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

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

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

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

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Agreement on Confidentiality

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

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

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

_____

Signature Date

_____

Chairperson's Signature Date

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

_____

Signature Date

Conflict of Interest Agreement Form for IEC Members

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

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

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

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

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

Agreement on Conflict of Interest

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

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

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

_____

Signature Date

_____

Chairperson's Signature Date

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

_____

Signature Date

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Confidentiality Agreement Form For Guest/ Observer Attendees to IEC Meetings

I, _____ (name), understand that I am being allowed to attend the Institutional Ethics Committee meeting scheduled on_____ at_____ am/pm as a Guest. The meeting will be conducted in the_____, All India Institute of Medical Sciences. During the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

_____ **Signature of the Guest**	_____ **Date**
_____ **Chairperson of IEC**	_____ **Date**

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the IEC -Chairperson and me.

_____

Signature of the Guest **Date**

Annexure – 14

Confidentiality Agreement Form for Subject Experts (Affiliated/ non affiliated to the institution)

I,_____

_____(Name and Designation) as a non-member of Institutional Ethics Committee (IEC) understand that the copy *I* copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the Guest	**Date**
Chairperson of IEC	**Date**

I,_____(name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

Signature **Date**

DEAN
Dr Panjabrao Alias Bhausahab Deshmukh
Memorial Medical College, Amravati

Initial Check list to verify completeness of documents submitted (Form 5)

For official use only **Proposal No. _____**

1. Three (03) copies of the proposal for regular ethics committee meeting along with a soft copy in CD format
2. Proforma (Form 1A or Form 1B) duly signed by the investigator(s), guides, co-guides, Head of concerned departments and Head of Institute, with date
3. Completed proforma (Form 2)
4. Participant/patient/volunteer information sheet written in dialogue format addressing the patient/participant in both English language and Hindi or Other local language
5. Consent forms (English and Hindi/Other local language) matching with those given Dr. PDMMC, Amravati. web site.
6. Assent form, if applicable

Proforma for research proposal involving human subjects to be submitted to the Institute Ethics Committee for approval (Form 1A)

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department and Institution.
6. Date of approval by Institute Research Cell:
7. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
8. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questiolmaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and Hindi/Other local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.
9. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available.
10. Usefulness of the project/ trial
11. Expected 'benefits' to volunteers/ community. 'Benefits' to other categories if any.
12. Explain all anticipated 'risks' (adverse events, injury, and discomfort) of the project, efforts taken to minimize the 'risks'. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
13. Agreement to report all Serious Adverse Events (SAE) to IEC-Dr. PDMMC, Amravati.
14. Other financial issues including those related to insurance.
15. An account of storage and maintenance of all data collected during the trial.
16. Research proposals approval by scientific advisory committee/Research Cell
17. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
18. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

19. Statement of conflicts of interest, if any.
20. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
21. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
22. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
23. Curriculum vitae of all the investigators with relevant publications in last five years.
24. Plans for publication of results/ positive or negative / while maintaining the privacy and confidentiality of the study participants.
25. Any other information relevant to the study.
26. Signature of the Principal Investigator with date.

Note:

1. No research project shall be/ can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institute Ethics Committee.
2. Submit three (03) copies of the Research Proposal along with Covering letter and 'soft copy' by email.
3. Proforma must be accompanied by Consent Form (Form 3A/3B) in English and Hindi/Other local language
4. Consent form should be accompanied with patient/participant information sheet in simple language and it should address to the subjects, in dialogue format.
5. Submissions will be received on all working days.
6. While submitting replies raised by the IEC, the candidates are advised to mention IEC reference number/s and also attach a copy of the comments of the IEC.
7. While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not affect the safety of the subject in anyway.

Proforma to be submitted to the Dr. PDMMC, Amravati. Institute Ethics Sub- Committee (Human Studies) for MD/MS/DM/M.Ch/Ph.D/MSc Students (for Thesis or Dissertation)/MBBS student projects (Form 1B)

Kindly submit 03 copies of proforma and consent forms in 2 parts (in English and Hindi/Other Local language) to the Member Secretary, Ethics (Human) committee, Dr. PDMMC, Amravati.

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Institute Research Cell:
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Ethical issues involved in the study:

    less than minimal risk/ minimal risk/ more than minimal risk to the study subjects

    [Along with the level of risk, the risks should be discussed in detail]
11. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications
12. Whether Consent forms part 1 and 2 in English and Hindi/Other local language are enclosed?

    (if the consent form in local language is not applicable, appropriate explanations must be provided)
13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
14. Whether soft copy of the proforma (CD) has been attached?
15. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Signature of the Investigators: Date:

Signature of the Guide: Date:

Signature of the Head of the Department: Date:

Signature of the Head of the Institute: Date:

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

General Format for Participant/Patient/Volunteer Information Sheet

Instructions

This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form (Form 3A or 3B) for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Hindi/Other local language(s) which can be understood by the participant

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

Consent Form for participants more than 18 years of age (Form 3A)

Participant Consent Form

Participant's Name:

Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. 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 the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant/
Thumb Impression : _____ Date: _____

Signature of the witness : _____ Date: _____

Signature of the investigator : _____ Date: _____

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Consent Form for participants less than 18 years of age (Form 3B)

Parents/Legally accepted representative (LAR) Consent Form

Participant's Name:

Address:

Parent/LAR's Name:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 12 to 18 years of age)

Signature of the parent/ LARI
Thumb Impression : _____ Date: _____

Signature of the witness : _____ Date: _____

Signature of the investigator : _____ Date: _____

Assent Form for participants of age 12 – 18 years (Form 3C)

Principal Investigator:

Name of Participant:

Title:

We are doing a research study. I am [you or your representative's name]

We are doing this study to find out [write the purpose of your study]

We are asking you to take part in this study because you [give reason]
But we will only take you if you allow us. If you do not want to do so your treatment will continue as usual. If you decide to take part now, but wish to discontinue later, you can tell us and we will take you out of the study.

Once you agree to take part, you will have to [mention procedures that will be done]

These procedures can [write about risks/discomforts]

It is possible that the study will help you feel better. It can also occur that you do not get any benefit but the information we get from you may help other children in future.

We have asked your parents [or guardian] their permission and it is all right with them.

Do not hesitate to ask questions. You can also ask us about anything later on if there are no questions right now.

	Child's signature/Thumb Impression
I have been explained about the study and I agree to take part in it.	

Child's Name:

Date:

Certificate by the Investigator (his/her representative obtaining assent):

	Tick one	Signature of the Investigator/representative
The child can read the assent form and was able to understand it		
The child was not capable of reading the assent form, but I verbally explained the information.		

Name of Investigator/ representative:

Date:

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Informed Consent Document For Drug Clinical Trial

(Table 03: New Drugs and Clinical Trial Rule 2019, dated 19th March 2019)

1. Checklist of informed consent documents for clinical trial subject:

1.1 Essential elements:

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

(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 Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

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

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

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

(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 be given 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 or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation 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 subject 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 that refusal 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 therapeutic effect.

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

(xvi) Any other pertinent information.

1.2 Additional elements, which may be required:

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

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

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

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

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

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

2. Format of informed consent form for Subjects participating in a clinical trial

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials: _____ Subject's Name:_____

Date of Birth/Age: _____

Address of the Subject _____

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 of trial related death).

Place Initial box (Subject)

(i) I confirm that I have read and understood the information [ ] Sheet dated _____ for the above study and have had 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, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific 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: _____ Date: ___/___/_____

Signature of the Witness: _____ Date: ___/___/_____

Name of the Witness: _____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

Informed Consent Document For Medical Device Clinical Investigation

(Table 08: G.S.R. 78(E), Medical Device Rule 2017, dated 31st January 2017)

Checklist for clinical investigation Subject's informed consent documents

1.1 Essential elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to Subject's medical records
8. Clinical investigation treatment schedule(s) and the probability for random assignment to each treatment (for randomised clinical investigation)
9. Statement describing the financial compensation and medical management as under:
   (a) In case of an injury occurring to the subject during the clinical investigation, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical investigation, whichever is earlier.
   (b) In the event of an investigation related injury or death, the Sponsor or his representative, whoever has obtained permission from the Central Licensing Authority for conduct of the clinical investigation, shall provide financial compensation for the injury or death.
10. An explanation about whom to contact for clinical investigation related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for paiiicipating in the clinical investigation
12. Subject's responsibilities on participation in the clinical investigation
13. Statement that participation is voluntary, that the Subject can withdraw from the clinical investigation at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Statement that there is a possibility of failure of investigational medical device to provide intended therapeutic effect.
15. Any other pertinent information.

1.2 Additional elements, which may be required

(a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
(b) Additional costs to the Subject that may result from participation in the clinical investigation.
(c) The consequences of a Subject's decision to withdraw from the investigation and procedures for orderly termination of participation by Subject.
(d) Statement that the Subject or Subject's representative will be notified in a timely manner

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

if significant new findings are developed during the course of the investigation which may affect the Subject's willingness to continue participation will be provided.

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

(f) Approximate number of Subjects enrolled in the clinical investigation

2. Format of informed consent form for Subjects participating in a clinical investigation -
Informed Consent form to participate in a clinical investigation

Clinical investigation Title:

Clinical investigation Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth/ Age: _____ Gender: _____

Address of the Subject: _____

Qualification: _____

Occupation: Student/Self-employed/Service/Housewife/Others (Please tick as appropriate)
Annual income of the subject: _____

Name and address of the nominee(s) and his relation to the subject _____
(for the purpose of compensation in case of clinical investigation related death).

Place initial box (Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above clinical investigation and have had the opportunity to ask questions. [ ]

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

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

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

(vi) I understand that in case of an injury occurring during the clinical investigation, free medical management shall be given as long as required. (vii) I understand that in the event of an investigation related injury or death, financial compensation for such injury or death shall be provided in accordance with the provisions of the Medical Device Rules, 2017.

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

Date:____/_____/_____

Signatory's Name: _____

Signature of the Investigator:_____

Contact Details (Telephone Number/ mobile) on which subject may contact:_____

Date:_ _ _/_ _ _ _/_ _ _ _ _

Clinical investigation Investigator's Name:

_____

Signature of the Witness_____ Date:____/____/_____

Name of the Witness:

_____

Address and contact details of the Witness:

_____

(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant).

DEAN
Dr. Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Check list for verification of proposals submitted to Institute Ethics Committee (Human studies) (Form 6)

For official use only **Proposal No.**

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy marker or statistical expert? (If Yes, please inform the Secretary as soon as possible, suggesting a suitable person)				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators' qualification, competence and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risk/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher's qualifications, competence and experience suitable to ensure safe conduct of the study?				
3 Is the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participant and the concerned committee adequately?				

	Yes	No	NA	Comments
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for patticipants who sustain injuries?				
6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
Informed consent				
I. Is the process for obtaining informed consent appropriate?				
2. Are the palticipants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research patticipants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
Confidentiality				
I. Will the researcher collect only the minimum information/samples required to fulfil the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
RigMs of the participants				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medica[illegible], Amravati

	Yes	No	NA	Comments
Fair participant selection				
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?				
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payment and other rewards?				
4. Are there any other/ legal/ social/ financial issues in the study?				

Additional Comments:

_____

_____

_____

Recommendation: Approve [ ] Reject [ ] Conditional Approval (please state the conditions)

_____

_____

_____

Name of Reviewer :

Signature :

Date :

Annexure – 25

Format for Six monthly progress of Project

IEC Reference No.: _____

Study title: _____

Name of the Principal Investigator: _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of six monthly progress report: From _____ to _____

Progress:

Adverse Effect if any:

Amendment if any:

If discontinuation, give reasons:

Progress:

Signature of Principle Investigator : _____

Date : _____

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati

Format for Communication of decision by IEC-Dr. PDMMC, Amravati

Study title:			
Principal Investigator:			
Name and Address of Institution:			
New review | | Revised review		| Expedited review |	
Date of review (DD/MM/YY): Date of previous review, if revised application:			
Decision of the IEC			
	Recommended		Recommended with suggestions
	Revision		Rejected
Suggestions/ Reasons/ Remarks:			
Recommended for a period of :			

Please note:

- Inform IEC immediately in case of any adverse events and serious adverse events.
- Inform IEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above. Annual report to be submitted to IEC
- Members of IEC have right to monitor the trial prior intimation.

Signature of Member Secretary
IEC-Dr. PDMMC, Amravati.

Format for Approval Notice by IEC-Dr. PDMMC, Amravati

Letter Ref. No. IEC.:

Date:

Date:

INSTITUTE ETHICS COMMITTEE APPROVAL NOTICE

Re: IEC Proposal No. _____: [Title] _____

To

Dr. [Name], Principal Investigator

Dear Dr. [Name]

The Institutional ethics committee Dr. PSMMC, Amravati had reviewed and discussed your application to conduct the clinical trial/study entitled

"_____On _____ (date).

The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated_____version No.(s)_____

(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure, dated_____ Version no_____ Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(d) Principal investigator's current Cun-iculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (Annexure I)

The following members of the ethics committee were present at the meeting held on (date, time, place).

_____ Chairperson of the ethics committee;

_____ Member-Secretary of the ethics committee;

_____ Name of each member with designation;

DEAN
Dr Panjabrao Alias Bhausaheb Deshmukh
Memorial Medical College, Amravati