3.3.1

Code of Ethics

Institutional Ethics Committee SOP & composition

Institutional Ethics Committee
JMF's ACPM Medical College
Dhule - 424001 (MS)

Standard Operating Procedure (SOP)

Prepared by

Dr. A.W. Patil
Professor & HOD
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ACPM Medical College,
Dhule

PROF. & H.O.D.
Dept. of Pharmacology,
A.C.P.M.Medical College,
DHULE - 424001. [M.S.]

Dr. N. V. Dravid
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Professor & Head,
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Approved By

DEAN
A.C.P.M.MEDICAL COLLEGE & HOSPITAL
DHULE

JMF'S A.C.P.M. MEDICAL COLLEGE & HOSPITAL DHULE

Standard Operating Procedure

Version: 01

SOP Reviewed on: 2nd January, 2020

Approved by

Dr. Arun Moray
Chairman IEC- ACPMMC
Professor & HOD
Department of Department of OBGY,
SBH GMC Dhule

Dr.Arun P. Moray
M.D. (Obst.& Gynac.)
Chairperson IEC

Dr. S. P. Wadgaonkar
Member Secretary IEC- ACPMMC
Professor & HOD
Dept of Ophthalmology
ACPM Medical College, Dhule

Dr.Surendra P. Wadgaonkar
M.S. (Ophthalmology)
Member Secretary IEC

JMF'S A.C.P.M. MEDICAL COLLEGE & HOSPITAL DHULE

INSTITUTIONAL ETHICS COMMITTEE

JMF's ACPM MEDICAL COLLEGE DHULE – 424001

Annexure

File No. EC/20/000129

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 28-Aug-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Arun Pundalik Morey	MBBS (MD-Obstetrics and Gynaecology)	Chair Person
2	Dr. Surendra Padmakar Wadgaonkar	MBBS (MS-Ophthalmology)	Member Secretary
3	Dr. Arun Waman Patil	MBBS (MD-Pharmacology)	Basic Medical Scientist
4	Dr. Sarika Prashant Patil	MBBS (MD- Preventive And Social Medicine)	Clinician
5	Dr. Yogesh M Borase	MBBS (MD-Anesthesiology)	Clinician
6	Dr. Nitin Naresh Kulkarni	MBBS (DGO,DNB-Obstetrics and Gynecology)	Clinician
7	Mr. Chandrashekhar Purushottom Kulkarni	BA (LLM)	Legal Expert
8	Mr. Sahaji Waman Shinde	BA (MA,M.Phil.,MSW)	Social Scientist
9	Mr. Vinay Rohidas Patil	BE (MBA)	Lay Person

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2b ea56c83bfbbe2154e399fb1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2020.08.28 16:56:15 +05'30'

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

JMF'S A.C.P.M. MEDICAL COLLEGE & HOSPITAL * DHULE *

Jawahar Medical Foundation's
Annasaheb Chudaman Patil Memorial
Medical College
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INSTITUTIONAL ETHICS COMMITTEE
JMF's ACPM MEDICAL COLLEGE DHULE

1. **Dr. Arun Morey (M.S. OBGY)**
   Chairman, Institutional Ethics Committee.
   HOD, Department of OBGY, S.B.H. Government Medical College Dhule

2. **Dr. S. P. Wadgaonkar (MS Ophthalmology)**
   Member Secretary, Institutional Ethics Committee.
   Professor and HOD, Department of Ophthalmology ACPM Medical College, Dhule

3. **Dr. A.W.Patil (MD Pharmacology)**
   Basic Medical Scientist Institutional Ethics Committee
   Professor and HOD, Department of Pharmacology ACPM Medical College, Dhule

4. **Dr. Sarika Prashant Patil (MD PSM)**
   Basic Medical Scientist, Institutional Ethics Committee
   Associate Professor, Department of Community Medicine, S.B.H. Government Medical College Dhule

5. **Dr. Yogesh Motilal Borse (MD Anesthesiology)**
   Clinician, Institutional Ethics Committee
   Associate Professor, Department of Anesthesiology, S.B.H. Government Medical College Dhule

6. **Dr. Nitin Kulkarni (DNB OBGY)**
   Clinician, Institutional Ethics Committee
   Professor, Department of OBGY, ACPM Medical College, Dhule

7. **Mr. Shahaji Vaman Shinde (BA. MA. M.Phil, M.S.W, Diploma in** Journalism)
   Social Scientist, Institutional Ethics Committee
   Director of Navnirmiti Sanstha (N.G.O.) Dhule

8. **Adv. C. P. Kulkarni (BA Hon's LLM)**
   Legal Expert Institutional Ethics Committee

9. **Mr. Vinay R. Patil (BE MBA)**
   Lay Person, Institutional Ethics Committee.

JMF'S A.C.P.M. MEDICAL COLLEGE & HOSPITAL * DHULE *

2. BASIC RESPONSIBILITIES

The basic responsibility of an IEC (Institutional Ethics committee) is to ensure a competent review of all ethics aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. Also to provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committees. The scientific evaluation should ensure technical excellence of the proposed study.

The responsibilities of an IEC can be defined as follows:-

1. To protect the dignity, rights and well being of the potential research participants.
2. To ensure that universal ethics values and international scientific Standards are expressed in terms of local community values and customs
3. To assist in the development and the education of a research community Responsive to local health care requirements
4. The ethics committee should exercise particular care to protect the rights, safety and wellbeing of all vulnerable subjects participating in the study.

Members should be conversant with the provisions of clinical trials under drugs & cosmetic act 1945, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

3 COMPOSITION & QUORUM

COMPOSITION:

IECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC. Ethics Committee shall consist of not less than eight to twelve members, and one among its members, who is from outside the institute, shall be appointed as Chairman; one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-medical and Nonscientific fields including lay public. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee.

The members representing 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.

Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

QUORUM REQUIREMENT

The new drug and clinical trial Rules 2019 come into force from march 19, 2019 and as per their guideline the ethics committee approving trials should have in the quorum at least one representative from the following groups….

1. One basic medical scientist (Preferably one Pharmacologist)
2. One Clinician
3. One legal expert
4. One social scientist /representative of non-governmental organization/philosopher/ ethicist/theologian or a similar person.
5. One lay person from the community.

4.CONFLICT OF INTEREST & TRAINING

CONFLICT OF INTEREST:

- There should be no conflict of interest by the members of IEC, Principal investigator, patient information related, results related, financial matters related (industries/ commercial companies/ownership or part-ownership of a company developing a new product), publication of data related, secondary interest like non- financial (personal, academic or political) etc.
- The investigators should declare such conflicts of interest in the application submitted to IEC for review.
- The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

TRAINING :

- Members should be conversant with the provisions of clinical trials under new Drugs and clinical trial rules 2019, Good Clinical Practice Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
- All members shall receive training for Ethical guidelines for biomedical research & GCP.
- Any new amendments will be periodically updated.

5.TERMS OF REFERENCE

- **Appointment & Duration**: The members will be appointed by Nomination, for not more than 3 years. This will be extended as per the IEC requirement. One third of New members nomination may considered after the completion tenure of nominated members
- **Policy for removal/replacement**: Willingness of the member to opt out/Continuously missing the meetings on more than 6-7 occasions. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.
- **Resignation:** A member if opts to resign should submit the application/Notice at least 15 days before so as to enable replacement accordingly
- **Frequency of meetings**: IEC-ACPMMC DHULE meeting will generally be called within four week of the Receipt of the proposal and submission of the study related documents OR As required in emergency/exceptional situation only.
- **Reasonable fees** will be charged to cover the expenses related to review and administrative processes. The processing fee will be Rs. 200/- for Protocols Submitted by Faculties & Students of JMFs ACPM Medical College Dhule, Rs.1000/- for outside proposals faculties of institutes, Rs. 1000/- for Ph.D. proposals, and Rs.5000/- for the sponsored trials/NCEs/outside clinicians
- **Honorarium** (Depending on Budget available)
    - **The IEC members** who are not affiliated with JMFs ACPM Medical College Dhule could be given a reasonable compensation minimum Rs.500/- to Rs.1000/- for the time spared for reviewing the proposals.
    - **Supporting staff Honorarium**: Services of one stenographer, one Clerk& one attendants from JMFs ACPM Medical College Dhule, will be utilized by the member secretary for maintaining records and all arrangements as required for the IEC meetings. An Honorarium of Rs.300/- to stenographer, Rs.200/- to clerk & Rs.100/- to Attendant shall be paid for all full review meetings.

JMF's A.C.P.M. MEDICAL COLLEGE & HOSPITAL * DHULE *

- All above financial aspects (review fees & honorarium) will be approved by the Dean/Principal/Head of the institute time to time
- All the documents pertaining to the ethics committee will be kept in the office of the Member Secretary Ethics Committee JMFs ACPM Medical College Dhule with all required facilities. All the documents shall be retained with strict confidentiality

6. REVIEW PROCEDURES

- ❖ The IEC should review every research proposal on human participants before the research is initiated.
- ❖ It should ensure that a scientific evaluation, including facilities and infrastructure of study sites, Justification of placebo in control group, has been completed by the members of IEC before keeping the proposal for ethics review
- ❖ The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and the justice issues.
- ❖ Experimental new clinical entities (NCEs) need to be approved by the DCGI. It will be mandatory for the PI to submit the copy of the same. No proposal shall be considered for the review if the DCGI permission is applied for/pending.
- ❖ For all sponsored studies conducted at JMFs ACPM Medical College Dhule It will be mandatory for Principal Investigator to submit the NO OBJECTION certificate from the Head of the department & Dean JMFs ACPM Medical College Dhule. Without NOC proposals will not be accepted.
- ❖ The details of the compensation paid to the subjects/family if suffered SAE will require to be submitted along with proposal.
- ❖ The IEC-ACPMMC makes it clear that proposals with incomplete documents will NOT be considered for review procedure; similarly, the proposals submitted must be paginated and total number of pages needs to be mentioned in the title page of Protocol.
- ❖ The committee will review approved research progress as and when thought necessary and will maintain a list of projects submitted approved/disapproved and thcir outcome.

The IEC's member-secretary/nominated person by the committee or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely,

1. Exemption from review,
2. Expedited review and
3. Full review

An investigator cannot decide that her/his protocol falls in the exempted category without approval from the IEC.

All proposals will be scrutinized to decide under which of the following three categories it will be considered:

A) Exemption from review

Proposals which present less than minimal risk fall under this category as may be seen in following situations: Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

a) When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

b) When interviews involve direct approach or access to private papers.

B) Expedited Review

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

a) Minor deviations from originally approved research during the period of approval (usually of one year duration).

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

c) 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.

C) 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. E.g. Collection of Blood Samples, prospective collection of biological specimens for research purposes by noninvasive means.

Full Review…. ***The ethics review should be done in formal meetings and EC should not take decisions through circulation of proposals. The committee should meet at regular intervals and should not keep a decision pending for more than 3 - 6 months.***

D) INTERIM REVIEW

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

a) Re-examination of a proposal already examined by thc IEC;

b) Research study of a minor nature such as examination of case records etc.;

c) An urgent proposal of national interest.

REVIEW PROCEDURES IN SELECTED & VULNERABLE POPULATION

- All procedures need to be followed of this SOP in all clinical studies. Special care needs to be taken by the PI & study team for vulnerable population.
- Pregnant or nursing women should not be participants of any clinical trial **except** such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.
- Children will not be involved in research that could be carried out equally well with adults. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
- **Vulnerable groups**: Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.
    - Research on genetics should not lead to racial inequalities;
    - Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
    - Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;
    - Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons
- The observations and suggestions of IEC should be given in writing in unambiguous terms in such instances.
- Special Audits will be done by the IEC members in these situations.

7. DECISION MAKING PROCESS

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

1. The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review, the Member Secretary will communicate the decision in writing.
2. A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest, which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes.
3. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed.
4. A negative decision should always be supported by clearly defined reasons.
5. An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.
6. The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
7. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
8. The principal investigator/co-invcstigator may be invited to present the protocol and offer clarifications in the meeting OR Proposals will be submitted to the quorum for opinion & views which will be communicated to the PI for explanations before considering for clearance. Representative of the patient groups or interest groups can be invited during meeting to offer their viewpoint.
9. Subject experts may be invited to offer their views, but not allowed to take part in the decision making process. However, her / his opinion must be recorded.

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

a) any amendment to the protocol from the originally approved protocol with proper justification;

b) Serious and unexpected adverse events and remedial steps taken to tackle them. ***It will be mandatory for the PI to forward this information of SAE to DCGI & other regulating Authorities involved within 24 hours.*** A copy of the same should be submitted to the IEC-ACPMMC

In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified in New drug and clinical trial rules 2019.

c) Any new information that may influence the conduct of the study.

11. The chairman will appoint & permit another person to act as chairperson for the meeting preferably a member outside the institute in his absence, the same should be noted in minutes of meeting.

12. Meetings are to be minuted by a member of IEC nominated by the Chairperson/ member secretary.

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

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

8. APPROVAL PROCEDURE

- Requires voting by show of hands by the members present at the meeting and the written opinion from those who are absent.
- Should an amendment to any study related documents, be it administrative in nature and not involving safety criteria, the Chairman/Secretary of the Committee, In writing may approve it without calling a full meeting. The Chairman/Secretary will inform other members of the committee of the amendments to the decision. The decision will be ratified at the next full committee meeting and this will be minuted.
- The decision of the ethics committee will be communicated within 2 days after the meeting. The applicants should collect the approval letter in person from the department of Ophthalmology ACPM Medical College Dhule.
- The committee will give its opinion on the project as....
  - Approved
  - Dis-approved (supported by clearly defined reasons)
  - Modification before approval on ethics grounds (supported by clearly defined reasons)
  - Discontinuation of approval of a previously approved project (supported by clearly defined reasons)
- The Ethics Committee Decision/Approval format will be as specified in the Appendix VIII of Drugs and cosmetics act 1945. After signature of all members who have attended the meeting on reviewed protocol.

9.RESPONSIBILITY OF PRINCIPAL INVESTIGATOR

- The committee expects from the Principal Investigator.
  - A report of clinical trial on a monthly basis.
  - A report of each serious event observed during the conduct of the study within the time frames. The PI should submit the SAE to Sponsors in case of sponsored study to be forwarded to DCGI and measures taken to resolve. A copy of the same to be marked to IEC-ACPMMC
  - To be kept informed of the amendments with defined reasons made to any study related documents and get the approval of the same from IEC before applying amendments.
  - To be kept informed about the study discontinuation with its reasons.
  - Mandatory to submit summary report after completion of the study.
  - No Data or part of data should be used for publication till the study is completed and the PI submits study completion report of the same to the IEC.
  - ***NO data/investigations/interventions will be done or recorded in the study participants <u>other than approved by the IEC.</u>***

<u>NOTE</u>: All above information if not submitted to the IEC within the time frames, the PI & co investigators / sponsors will be totally answerable during audits by the authorities.

10.RECORD KEEPING & FINANCIAL ASPECTS

RECORD KEEPING:

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. Records should be maintained for the following:

- The Constitution and composition of the IEC;
- The curriculum vitae of all IEC members;
- Standing operating procedures of the IEC;
- National and International guidelines;
- Copies of protocols submitted for review;
- All correspondence with IEC members and investigators regarding application, decision and follow up;
- Agenda of all IEC meetings;
- Minutes of all IEC meetings with signature of the Chairperson/Member secretary;
- Copies of applications & decisions communicated to the applicants;
- Record of all notification issued for premature termination of a study with a summary of the reasons;
- Final report of the study including microfilms, CDs and Video recordings, etc. will be maintained after the receipt of the same.
- All records to be safely maintained after the completion/termination of the study for at least a period of 5 years, if it is not possible to maintain the same permanently.

FINANCIAL ASPECTS:

For all sponsored studies, IEC processing fees Cheque to be issued in the name of **"Institutional Ethics Committee,** JMFs ACPM Medical College Dhule"

11. CONTENTS OF PROTOCOL

1. It will be mandatory to prepare the protocol as per New drug and clinical trial rules 2019 guidelines. All the heads as below needs to be covered, No proposal will be accepted if the following details are not given…

1. Clear and explanatory research tittle, details of background of the research, study objectives, study design, section criteria's, study population, sample size, interventional product details in all perspective, informed consent in vernacular languages as applicable, procedures that will be followed, investigations, procedures of data recording, any tech information, Data and safety monitoring procedures as applicable.
2. For all sponsored studies conducted at ACPM Medical College Dhule
   … It will be mandatory for Principal Investigator to submit the NO OBJECTION certificate from the Head of the department & Dean ACPM Medical College Dhule. Without NOC proposals will not be accepted.
3. All Details of Funding agency / Sponsors…..and fund allocation / utilization/patient remuneration,/ Signed Indemnity Agreement./Investigator's agreement with the Sponsors, Proposed compensation and reimbursement of incidental expenses. **Undertaking in this regard of PI & Sponsors will be compulsory.**
4. CTRI Registration as Applicable.
5. Permission letters from licensing authorities (DCGI & others)
6. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
7. A description of plans to withdraw or withhold standard therapies in the course of research.
8. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and vernacular languages. (As specified in the Appendix V of Drugs and cosmetics act 1945).
9. The detail plans for statistical analysis of the study
10. Statement of privacy & confidentiality of personal data
11. Investigators brochure

12. Undertaking by the investigator as per New drug and clinical trial rules 2019
13. Recent curriculum vitae of the Investigators indicating qualification and experience
14. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
15. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to overdose should be included.
16. SAE reporting format as applicable for all interventional studies… as specified in the Appendix XI of Drugs and cosmetics act 1945/Pharmacovigilance guidelines.
17. All Details of Funding agency/Sponsors and fund allocation/utilization/patient remuneration/signed indemnity/investigators agreement with sponsors, etc. for the proposed work. Proposed compensation and reimbursement of incidental expenses. Undertaking in this regard of PI & Sponsors will be compulsory.
18. Storage and maintenance of all data collected during the trial.
19. Plans for publication of results – positive or negative – while maintaining the privacy and confidentiality of the study participants.
20. A statement on probable ethics issues and steps taken to tackle the same
21. All other relevant documents related to the study protocol including regulatory clearances.
22. Agreement to comply with national and international GCP protocols for clinical trials.
23. Detail case record form covering fine details of observation to be recorded.
24. A statement stating that NO other data/investigations/interventions will be done or recorded in the study participants other than approved by the IEC.
25. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/authority like Drug Controller General of India (DCGI)
26. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
27. A statement on conflict-of-interest (COI), if any
28. Any other relevant information is to be documented.
29. Complete photo copies of essential references.

12. SUBMISSION OF APPLICATION

- The principle investigator should submit an appropriate application in a prescribed format only.
- The PI should submit…one copy of complete protocol in the required format along with references, + detail case-record form + compulsory appendices and formats as required + other specific information .together as one binded copy
- In addition, separate seven copies of only synopsis (not more than 3-4 pages).
- The application and other formats will be made available in the department of Pharmacology JMFs ACPM Medical College Dhule, as soft copies.

Dr. Arun P. Moray	Dr. S. P. Wadgaonkar
Chairman IEC-ACPMMC	Member Secretary
Prof. & HOD	Prof. & HOD
Department of OBGY	Department of Ophthalmology
SBH GMC Dhule	ACPM Medical College Dhule

Guidelines Referred:

1. *Ethics Guidelines for Biomedical Research on Human Subjects ICMR, New Delhi, 2000.*
2. *Ethics Guidelines for Biomedical Research on Human Participants ICMR 2006.*
3. *Ministry of Health & Family welfare (department of Health) Notification in the "The Gazette of India" New Delhi ...1st Feb 2013*
4. *Drugs and Cosmetics (Third Amendment) Rules, 2013. - NOTIFICATION Dated 8th February, 2013...*
5. *HANDBOOK FOR GOOD CLINICAL RESEARCH PRACTICE (GCP) GUIDANCE FOR IMPLEMENTATION...WHO*
6. *Central Drugs Standard Control Organization Ministry of Health | Govt. of India*
7. *New drug and clinical trial rules 2019*

INDIAN COUNCIL OF MEDICAL RESEARCH

Institutional Ethics Committee (IEC) of ICMR Headquarters Office,

Ramalingaswami Bhawan, New Delhi

Model form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal)

Proposal Title:

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI / Collaborators 1.			
2.			
3.			
Please attach detailed Curriculum Vitae of all Investigators (with subject specific Publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :

1. **Indian** : a) Government ☐ Central ☐ State ☐ Institutional ☐
   b) Private ☐
2. **International** : Government ☐ Private ☐ UN agencies ☐
3. **Industry** : National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget :

Institutional Ethics Committee (IEC) of ICMR Headquarters Office,

Ramalingaswami Bhawan, New Delhi

1.Type of Study :

☐ Clinical ☐ Epidemiological ☐ Behavioral

☐ Other Specify ----------

Whether :

☐ Multicentric ☐ Single center

2. Status of Review :

☐ New ☐ Revised

3. Clinical Trials:

Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of :

☐ Drug ☐ Devices ☐ Vaccines

ii.

☐ Indian Systems of Medicine/ Alternate System of Medicine

☐ Any other ☐ NA

iii. Is it approved and marketed

☐ In India ☐ Other countries, specify

☐ UK & Europe

☐ USA

iii. Does it involve a change in use, dosage, route of administration? YES/ NO

If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained? YES/ NO

If yes, Date of permission :

iv. Is it an Investigational New Drug? YES/ NO

If yes, IND No:

a). Investigator's Brochure submitted YES/ NO

b). *In vitro* studies data YES/ NO

c). Preclinical Studies done YES/ NO

d). Clinical Study is : Phase I / Phase II / Phase III / Phase IV

e). Are you aware if this study/similar study is being done elsewhere ? YES/ NO

If Yes, attach details :

INDIAN COUNCIL OF MEDICAL RESEARCH

Institutional Ethics Committee (IEC) of ICMR Headquarters Office,

Ramalingaswami Bhawan, New Delhi

4. Brief description of the proposal – Introduction, review of literature, aim(s) & Objectives, justification for study, methodology describing the potential risks & benefits, Outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects:

ii. Duration of study:

iii. Will subjects from both sexes be recruited YES/ NO

iv. Inclusion / exclusion criteria given YES/ NO

v. Type of subjects: Volunteers / Patients

vi. Vulnerable subjects YES/ NO

(Tick the appropriate boxes)

- ☐ Pregnant women
- ☐ Children
- ☐ Elderly
- ☐ Fetus
- ☐ Illiterate
- ☐ Handicapped
- ☐ Terminally ill
- ☐ Seriously ill
- ☐ Mentally challenged
- ☐ economically & socially backward
- ☐ any other

vii. Special group subjects YES/ NO

(Tick the appropriate boxes)

- ☐ Captives
- ☐ Institutionalized
- ☐ Employees
- ☐ Students
- ☐ Nurses/dependent staff
- ☐ Armed Forces
- ☐ Any other

6. Privacy and confidentiality

i. Study involves –

- ☐ Direct Identifiers
- ☐ Indirect Identifiers/coded
- ☐ Completely anonymised/ delinked

ii. Confidential handling of data by staff YES/ NO

7. Use of biological/ hazardous materials

i. Use of fetal tissue or abortus YES/ NO

ii. Use of organs or body fluids YES/ NO

iii. Use of recombinant/gene therapy YES/ NO

If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained? YES/ NO

iv. Use of pre-existing/stored/left over samples YES/ NO

v. Collection for banking/future research YES/ NO

vi. Use of ionising radiation/radioisotopes YES/ NO

If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? YES/ NO

vii. Use of Infectious/biohazardous specimens YES/ NO

viii. Proper disposal of material YES/ NO

ix. Will any sample collected from the patients be sent abroad ? YES/ NO

If Yes, justify with details of collaborators

a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? YES/ NO

b) Sample will be sent abroad because (Tick appropriate box):

- ☐ Facility not available in India
- ☐ Facility in India inaccessible
- ☐ Facility available but not being accessed.
- ☐ If so, reasons…

8. Consent :

- ☐ Written
- ☐ Oral
- ☐ Audio-visual

i. Consent form : (tick the included elements)

- ☐ Understandable language
- ☐ Statement that study involves research
- ☐ Sponsor of study
- ☐ Purpose and procedures
- ☐ Risks & Discomforts
- ☐ Benefits
- ☐ Compensation for participation
- ☐ Compensation for study related injury
- ☐ Alternatives to participation
- ☐ Confidentiality of records
- ☐ Contact information
- ☐ Statement that consent is voluntary
- ☐ Right to withdraw
- ☐ Consent for future use of biological material
- ☐ Benefits if any on future commercialization eg. genetic basis for drug development

*If written consent is not obtained, give reasons:

ii. Who will obtain consent?

- ☐ PI/Co-PI
- ☐ Nurse/Counsellor
- ☐ Research staff
- ☐ Any other

9. Will any advertising be done for recruitment of Subjects ?

(posters, flyers, brochure, websites – if so kindly attach a copy) YES/ NO

10. Risks & Benefits:

i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? YES/ NO

ii. Is there physical / social / psychological risk / discomfort? YES/ NO

If Yes,

- ☐ Minimal or no risk
- ☐ More than minimum risk
- ☐ High risk

iii. Is there a benefit a) to the subject ? Direct / Indirect

b) Benefit to society

11. Data Monitoring

i. Is there a data & safety monitoring committee/ Board (DSMB)? YES/ NO

ii. Is there a plan for reporting of adverse events ? YES/ NO

If Yes, reporting is done to :

☐ Sponsor ☐ Ethics Committee ☐ DSMB

iii. Is there a plan for interim analysis of data? YES/ NO

vi. Are there plans for storage and maintenance of all trial database? YES/ NO

If Yes, for how long ?

12. Is there compensation for participation? YES/ NO

If Yes,

☐ Monetary ☐ In kind

Specify amount and type:

13. Is there compensation for injury? YES/ NO

If Yes,

☐ by Sponsor ☐ by insurance company

☐ by Investigator ☐ by any other

14. Do you have conflict of interest? YES/ NO

(financial/nonfinancial)

If Yes, specify :

INDIAN COUNCIL OF MEDICAL RESEARCH

Institutional Ethics Committee (IEC) of ICMR Headquarters Office, Ramalingaswami Bhawan, New Delhi

Checklist for attached documents:

- Project proposal – 12 Copies YES/ NO
- Curriculum Vitae of Investigators YES/ NO
- Brief description of proposal YES/ NO
- Patient information sheet YES/ NO
- Informed Consent form YES/ NO
- Investigator's brochure for recruiting subjects YES/ NO
- Copy of advertisements/Information brochures YES/ NO
- Copy of clinical trial protocol and/or questionnaire YES/ NO
- HMSC/DCGI/DBT/BARC clearance if obtained YES/ NO

Place: Signature & Designation of PI/Co-PI/Collaborator

Date:

Ref.No.ETH.Com/ / Date-

INSTITUTIONAL ETHICS COMMITTEE

APPROVAL OF ETHICS COMMITTEE

To

Dr.

JMFs ACPM Medical College Dhule

Dear Doctor,

The Institutional Ethics Committee meeting of JMFs ACPM Medical College Dhule held on at Date & Time reviewed and discussed your application to conduct the clinical trial entitled:

Title

The following documents were reviewed.

Trial Protocol (including protocol amendment)

(a) Patient information sheet and informed consent form in English, Hindi & Marathi

(b) Investigator's Brochure.

(c) DCGI Approval.

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

(e) The following members of the ethics committee were present at the meeting.

We approve the trial to be conducted in the present form.

The Institutional Ethics Committee meeting of JMFs ACPM Medical College Dhule expect to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/ informed consent and asks to be provided a copy of the final report.

Chairman
IEC, JMFs ACPM MC Dhule

Member Secretary
IEC, ACPMMC, JMFs ACPM MC Dhule