



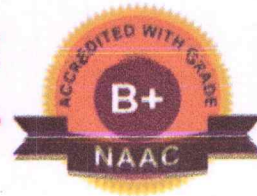
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Dr. Ulhas Patil Homoeopathic Medical College and Hospital, Jalgaon Kh.

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Annexure - X

Details of Institutional Ethical Committee and Research advisory committee

A) Details of Institutional Ethical Committee

Sr.No.	Name of Ethical Committee Member	Designation
1	Dr. Ulhas V Patil	Chairperson
2	Dr. R. K. Mishra	Member Secretary
3	Dr. Chandrayya Kante	Member, Clinician (Modern)
4	Dr. Chimanlal D Sarang	Member, Clinician (Modern)
5	Dr. Bapurao Bhite	Member (Modern Pharmacologist)
6	Dr. Aditya Dilipkumar Patil	Pharmacology (Homoeopathy)
7	Mrs. Jigyasa Mahendra Singh	Member, Social Scientist
8	Dr. Bhushan Sureshrao Wankhade	Member, Philosopher/Ethicist/Theologian
9	Mr. Lalit Bhagwat Mahajan	Member, Lay Person
10	Mrs. Vishakha Ganvir	Member, Expert from Nursing Science
11	Dr. Jaywant Nagulkar	Member, Expert of Physiotherapy
12	Dr. Abhishek Achalpurkar	Member, Clinician (Homoeopathy)
13	Dr. Harshal Borole	Member, Clinician (A)

Date:





Signature, Name and stamp of

Dean/Principal/Director

Principal

Dr. Ulhas Patil Homoeopathic Medical College & Hospital, Jalgaon Kh.

1. Hard Copy & Soft Copy of this Annexure must be submitted to the University
2. The information must be made available on the College website



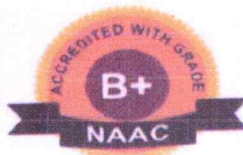
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STANDARD OPERATING PROCEDURES

DR. ULHAS PATIL HOMOEOPATHIC MEDICAL COLLEGE AND HOSPITAL – INSTITUTIONAL ETHICS COMMITTEE (DUPHMC-IEC)

GODAVARI FOUNDATION

Version 1.

Prepared by

Assoc. Prof. (Dr.) Aditya D Patil

Approved & Confirmed by

Founder & President, Hon. Dr. Ulhas Patil,

Chairperson, IEC, DUPHMC

&

Principal, Prof. (Dr.) Rakesh Kumar Mishra,

Member Secretary, IEC, DUPHMC




Dr. Rakesh Kumar Mishra
Principal

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1. Description of Standard Operating Procedures of Dr. Ulhas Patil Homoeopathic Medical College & Hospital Institutional Ethics Committee (DUPHMC-IEC)

1.1. Standard operating procedures of Dr. Ulhas Patil Homoeopathic Medical College and Hospital Institutional Ethics Committee herein after referred as "DUPHMC-IEC SOP" has been adopted by DUPHMC-IEC, to ensure the protection of rights and welfare of human participants in biomedical, experimental and behavioral research conducted at Dr. Ulhas Patil Homoeopathic Medical College and Hospital, Jalgaon (DUPHMC).

1.2. The Objective of DUPHMC-IEC SOP is to maintain efficient and effective functioning of DUPHMC-IEC. This SOP aims to ensure conduct of quality research in accordance with the ICMR/NCH guidelines for biomedical research on human subjects.

1.3. All the members of DUPHMC-IEC are the holders of DUPHMC-IEC SOP. The appointment order of members clearly mentions about the compliance of all members with the guidelines, roles and responsibilities mentioned in DUPHMC - IEC SOP.

1.4. DUPHMC-IEC is revised annually, and the printed copy of revised SOP will be made available to all members after approval from Chairperson, DUPHMC-IEC. Member secretary and one/two designated members of DUPHMC-IEC will do the revision. In addition to the annual revision, amendments will be done as and when required (in case of change of member/members, revision of ICMR/NCH guidelines). On amendment, electronic version of the SOP will be made available to members within seven days of amendment. The printed version will be made available only once in a year.



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2. Introduction to DUPHMC-IEC:

The DUPHMC-IEC reviews all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all research participants before approving the research proposals. This ethics committee takes up reviews of research proposals from Dr. Ulhas Patil Homoeopathic Medical College and Hospital.

The DUPHMC-IEC will ascertain whether all cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence and justice are taken care in the research involving human participants, conducted in DUPHMC. The DUPHMC-IEC will review all research projects to be conducted at the institution irrespective of whether the research project is funded or non-funded and irrespective of funding agency. The DUPHMC-IEC will provide advice to the researchers on scientific and all ethical aspects of research.

3. Goals and Objectives of DUPHMC-IEC:

3.1. Goals of DUPHMC-IEC:

- 1) To protect the dignity, rights and wellbeing of the current and potential research participants.
- 2) To ensure that universal ethical 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.

3.2. Objectives of DUPHMC-IEC:

- 1) To review the research proposals in an unbiased manner, without compromising the scientific quality and ethical principles in conduct of biomedical, experimental and behavioral research.




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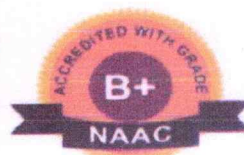
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- 2) To advice and educate the researchers on ethical guidelines in conducting research involving human participants.
- 3) To be updated with the relevant guidelines and regulations on research, research ethics and good clinical practice.
- 4) To monitor the progress of approved research proposals with regard to compliance of protocol and ethical principles.

4. Appointment of DUPHMC-IEC:

The Principal of Dr. Ulhas Patil Homoeopathic Medical College and Hospital, Jalgaon will appoints the members of DUPHMC-IEC including chairperson based on their competence, experience and integrity. He sends an official request letter to the members who will confirm their acceptance to the Principal by providing all required information such as curriculum vitae and certificates of training on research ethics and good clinical practice. The consent letter includes consent from the member, declaration of maintaining confidentiality of research project- related data/documents/discussions and willingness to get updated on research ethics, good clinical practice and regulations on human research. On receiving this consent, principal will issue the final appointment order. (Details of format cited in Annexure 1 to 6.)

5. Composition of DUPHMC-IEC:

5.1. The DUPHMC-IEC is multi-disciplinary and multi-sectoral in composition. It is independent and has 13 members. There is a mix of medical and non-medical members.




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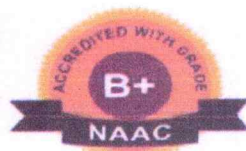
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5.2. Composition of Ethics Committee:

Sr. No.	Name	Qualifications and Affiliations	Designation in DUPHMC-IEC
1	Dr.Ulhas Patil	M.D Gynaecology Founder & President Godavari Foundation	Chairperson
2	Dr.R.K Mishra	M.D (Homoeopathy) Principal (DUPHMC)	Member Secretary
3	Dr.Chandriya Kante	M.D (Medicine)	Member, Clinician (Modern)
4	Dr.Chimanlal Dayabhai Sarang	M.D Medicine	Member, Clinician (Modern)
5	Dr.Bapurao Bhite	MBBS	Modern Pharmacologist
6	Dr.Aditya Dilip Kumar Patil	M.D (Homoeopathy)	Pharmacology (Homoeopathy)
7	Mrs.Jigyasa Mahendra Singh	M.A Sociology	Member, Social Scientist
8	Dr.Bhushan wankhade	M.D (Homoeopathy)	Member, Philosopher/Ethicist/Theologian
9	Mr.Lalit Mahajan	B. Com	Member, Lay Person
10	Mrs.Vishakha Ganvir	M.Sc Nursing	Member, Expert from Nursing Sciences
11	Dr.Jaywant Nagulkar	MPTH	Member, Expert of Physiotherapy
12	Dr. Abhishek Achalpurkar	M.D (Homocopathy)	Member, Clinician - Homeopathy
13	Dr. Harshal Borole	M.D Ayurveda	Member, Clinician - Ayurveda

5.3. Requirements for Membership:

1) Tenure of the members is three years. After the end of tenure, new members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience



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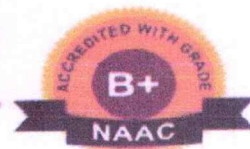
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- 2) A member can tender resignation to principal, through the chairperson after serving one month advance notice.
- 3) Principal, DUPHMC can replace a member of IEC as and when required.
- 4) During the term, Principal, DUPHMC can disqualify any member if the contribution is not adequate and /or there is a non-availability of the member for continuous three months.
- 5) Each member is required to sign the confidentiality agreement.

6. Roles and Responsibilities of Members of DUPHMC-IEC:

- 1) All members are expected to review the research proposals and attend the ethics committee meetings and participate in the discussions and deliberations.
- 2) To review the revised submissions, additional submissions, progress reports and final reports.
- 3) To review the reports of serious adverse events and recommend appropriate actions.
- 4) To carry out monitoring visits at study sites as and when needed.
- 5) To maintain confidentiality of the documents and deliberations of ethics committee meetings.
- 6) To declare conflict of interest if any, to the chairperson.
- 7) To participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

8) Chairperson:

- i) To conduct meetings and to be accountable for functioning of the committee
- ii) To ensure active participation of all members in all discussions and deliberations
- iii) Handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data




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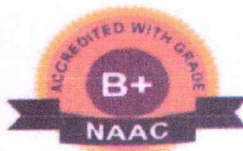
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iv) To ratify the minutes of previous meetings

v) To review serious adverse events with causality assessment

9) Member secretary:

i) To organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

ii) To schedule IEC meetings, prepare the agenda and minutes

iii) To organize IEC documentation, communication and archival

iv) To arrange for training of IEC secretariat and members

v) To ensure that SOPs are updated as and when required

vi) To ensure adherence of IEC functioning as per SOPs

vii) To prepare for and respond to audits and inspections

viii) Will function as chairperson in his absence; Helps the chairperson in recording minutes of meetings, sorting out the research proposals for review, documentation and in preparation for audits and inspections.

7. Conduct of DUPHMC-IEC Meetings:

7.1. Frequency: Meeting of DUPHMC-IEC is conducted once in Three months. Additional meetings will be conducted depending on the number of proposals received and pending for decision. Meeting notice will be sent atleast one week in advance to the members.

7.2. Responsibility for conducting meetings: Member secretary is responsible for organizing the meetings of DUPHMC-IEC, communicating with all the concerned, and maintaining records. He/she will prepare the minutes of the meeting and get it approved by chairperson and all the members. Chairperson is responsible for conducting the meeting. In case of anticipated/unexpected absence of chairperson, member secretary will conduct the meeting. If both chairperson and member




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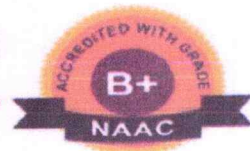
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secretary are absent, then an alternate chairperson will be elected from the members present, who will conduct the meeting.

7.3. Quorum Requirements: Quorum should be a minimum of 50% of the members + one. No decision will be considered valid without fulfilling the quorum. It is ensured that the quorum comprises of both medical and non-medical members. It is also ensured minimum two non-affiliated members are part of the quorum.

7.4. Independent Subject Experts: DUPHMC-IEC maintains a panel of subject experts who are consulted for review of research proposals and may be invited to the meeting in case of special requirements and absence of any regular member (Example. Pharmacologist, pediatrician, psychiatrist, physician etc). These members will not have the voting rights.

8. Procedure of applying for ethical clearance:

8.1. The DUPHMC-IEC receives research proposals for review on all working days from 10 AM to 4 PM. All proposals should be submitted atleast 10 days in advance (before the meeting of DUPHMC-IEC) to the DUPHMC-IEC. Investigators should submit proposals to the secretariat for review as per the guidelines given. The DUPHMC-IEC has a checklist for the documents to be submitted along with the research proposals.

The list of documents required for EC submission is as follows –

- 1) Covering letter to the member secretary
- 2) Project submission application form for initial review
- 3) The correct version of the research proposal: 12 sets of hard copies and one soft copy
- 4) Relevant administrative approvals (if applicable)
- 5) Memorandum of understanding in case of studies involving collaboration with other institutions




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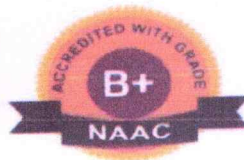
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Member secretary will go through (screening for documents to be submitted to DUPHMC-IEC) the proposals which are exempted from review, AND get the decision ratified in the full committee meeting Exceptions : when research on educational tests, survey 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

9.1.2. Expedited Review: The proposals that pose "no more than minimal risk" are considered for expedited review. Expedited review will be conducted by chairperson, member secretary and 1-2 designated members. The approval granted through expedited review will be ratified at the next full committee meeting.

In following situations, expedited review will be done.

- Minor deviations from originally approved through full review by the IEC,
- Revised proposal previously approved through full review or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis
- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples
- Research involving clinical documentation materials which are non-identifiable (data, documents, records)
- Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigator(s)
- Revised proposal previously approved through expedited review, full review or continuing review of approved proposals
- Minor deviations from originally approved research causing no risk or minimal risk
- Progress/annual reports where there is no additional risk e.g. activity limited to data analysis.




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

9.1.3. Full Review : All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review

i) All studies involving interventions involving trials on drugs or combinations of drugs

ii) Studies involving vulnerable population even if the risk is minimal

iii) Collection of blood samples by finger prick, heel prick, ear prick or venipuncture

iv) Collection of peritoneal fluid, pleural fluid, ascitic fluid and cerebrospinal fluid

v) Collection of biological specimen by research purposes by non invasive means – skin appendages, dental procedures ,excreta and external secretions, stimulated or unstimulated saliva collection, placenta removed at delivery , amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, buccal scrapings, skin swab or mouth washings, sputum

vi) Use of medical devices for study population such as implants and physical sensors

vii) Use of electrocardiography, electroencephalography, echocardiography, thermography, ultrasound and other imaging techniques, Doppler blood flow

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

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




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IX) Collection of data from voice, video, digital or image recordings made for research purposes

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

9.2. Aspects Considered During Review of Research Proposal:

Scientific design and conduct of the study:

1) Use of valid scientific methods

2) Social Values: The research must have anticipated social value, and outcome should be relevant to the health problems of the society

3) Benefit-Risk Assessment: The benefits must justify the risk inherent in the research. Risks may be physical, psychological, economic, or social; Withdrawal criteria, and rescue medication or procedures

4) Selection of the Study Population and Recruitment of Research Participants : To ensure voluntary recruitment, and fair selection of participants as per inclusion and exclusion criteria; participant is given option to opt out without the routine care being affected; No individuals or group of persons must bear the burdens of participation in research without any benefits except in studies where healthy volunteers are involved; Vulnerable group is not recruited unless proper justification is provided

5) Payment of participation and Compensation Procedures, without inducement but, reimbursing for incurred cost and convenience

6) Protection of research participant's privacy and confidentiality

7) Community considerations : due respect given to community and interests are protected ; no stigma or discrimination ensues from the proposed research ; plans




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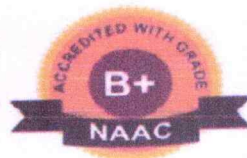
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for communication of results back to the community at the end of study; plan for dissemination of benefits of research to the community

8) Qualifications of investigators and assess adequacy of study sites

9) Disclosure of potential conflicts of interest

10) Review of informed consent process

The review of proposals by members is documented in review forms (Annexure 6), and proceedings of ethics committee.

10. Decision Making Process in DUPHMC-IEC:

10.1. Full Committee Meeting:

10.1.1. All proposals that are determined to undergo full committee review are deliberated and the decision about the proposal taken at a full committee meeting. IEC members are given enough time to review the documents sent. The period is minimum 1 week except for emergency research

10.1.2. A meeting will be considered valid only if the quorum is filled, which is maintained throughout the meeting.

10.1.3. The chairperson welcomes the members and member secretary introduces the agenda.

10.1.4. If a member has declared a conflict of interest for a proposal then this is submitted in writing to the chairperson before the meeting. This will be recorded in minutes.

10.1.5. List of absentee members is informed.

10.1.6. Ratification of the minutes of the previous meeting and exempt review, expedited review is done in the meeting




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10.1.7. Principal investigators of research proposals categorized for full review will be called to present the proposals in the full committee meeting.

10.1.8. Decision will be taken on a broad consensus.

10.1.9. **Voting:** If members have difference of opinion on approval, disapproval, request for modifications or information, suspension or termination of the research proposal, then voting will be done and majority vote will be considered for decision making. The voting is done in writing, submitted to chairperson who in turn will announce the decision. If a member is involved in a research project as an investigator, she/he will not participate in voting, and will not be present during voting/deliberations on that project. Subject experts who may be called too full committee meeting to offer their views will not have participate in voting. Only their opinion is recorded.

10.2. Decision: The decisions taken in the meeting are as follows:

- 1) Approval –with or without suggestions or comments
- 2) Resubmission - Modifications are suggested. After resubmission, if the modifications are minor, member secretary will review or expedited review will be done. For major modifications, the proposal is placed for full review and placed before the full committee for reconsideration.
- 3) Not Approved – Clearly defined reasons will be given for not approved/termination.

The decision of the IEC communicated to principal investigator. All communications are done by member secretary (or elected member in his absence). The communication of the decision will include:

- 1) Name and address of IEC
- 2) The date and place of decision
- 3) The name and designation of investigators
- 4) Protocol no. given by IEC




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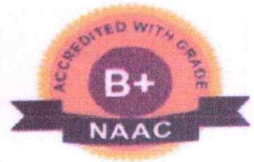
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- 5) Title of the research proposal reviewed
- 6) Version No., date, amendment no. of the protocol
- 7) List of documents reviewed -clear description of these documents along with version No., and date.
- 8) List of IEC members who attended the meeting-clear description of their role and affiliation
- 9) A clear statement of decision reached
- 10) Any advice by the IEC to the applicant including the schedule /plan of ongoing review by the DUPHMC-IEC
- 11) In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed
- 12) In case of rejection, reasons for rejection will be clearly stated
- 13) Signature of member secretary with date.

The investigator is asked to register the study in Clinical Trial Registry of India (CTRI). Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH is expected to register the trial in the CTRI before enrollment of the first participant.

10.3. Validity of Approval: The approval will be granted for the whole duration of the proposed research. However, the validity of the approval letter is only up to one year. Depending on the risk involved, the progress of the project may be monitored annually. The approval will be continued if progress is satisfactory. The decision of DUPHMC-IEC may be reversed if DUPHMC-IEC receives information that may adversely affect the benefit/risk assessment. (The format of decision letter is given in Annexure-7 & 8.)




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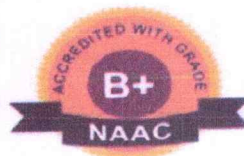
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11. Continuing Review:

11.1. The ongoing research will be reviewed at regular intervals of at least once a year. In case of clinical trials, this review will be done once in six months. The IEC evaluates progress of ongoing projects, serious adverse event reports at site and other sites, protocol deviations/violations, any new information pertaining to the research and assess final reports of all research activities.

11.2. In case of serious adverse events, for regulatory trials applicable regulations must be complied with. The DUPHMC-IEC will ensure compliance by the investigator.

11.3. DUPHMC-IEC examines the measures taken for the medical management of serious adverse events. Participants should not have to bear costs for the management of study related injury whether they are in the intervention or not. DUPHMC-IEC ensures that compensation is paid for research injuries if applicable, as determined by it and regulatory requirement where applicable.

11.4. For protocol deviations/violations the IEC examines the corrective actions. If the violations are serious the IEC may halt the continuation of the study. The IEC may report to Institutional head in case of continuing non-compliance to ethical standards. Declaration of Plagiarism & AI also needs to be reported during submission. (As per format cited in Annexure 9 & 10.)

11.5. The IEC will also seek the reports of monitoring done by the sponsor and Data and Safety Monitoring Board (DSMB). Format for reporting adverse events is to be followed as per <https://suraksha.ayush.gov.in/> mentioned under pharmacovigilance portal. Investigators are asked to submit progress report once in six months (clinical trials) or one year (studies other than clinical trials). Final report is submitted by principal investigator.

12. Site Monitoring: DUPHMC-IEC has a mechanism to monitor the approved study of clinical trials, till completion of research to check for compliance or improve the function. Monitoring will be "not for cause" or "for cause", and will be decided at a full committee meeting. "For cause" monitoring is done in case of:




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- 1) High number of protocol violations
- 2) Large number of proposals carried out at the study site or by the same investigator
- 3) Large number of serious adverse events
- 4) High recruitment rate
- 5) Complaints received from patients
- 6) Any media report
- 7) Adverse information received from any other source
- 8) Noncompliance to IEC directions
- 9) Misconduct by the investigator

“Not for cause /routine” monitoring is done for proposals that have a high risk, vulnerable participants. This will be decided at the continuing review.

13. Responsibilities of Investigators:

13.1. Investigators is responsible to generate and document and report the data as per good clinical practice guidelines of CDSCO (Central Drugs Standard Control Organization), Directorate General of Health Services, Government of India, ICMR guidelines for Biomedical Research on Human Participants and all applicable statutory provisions.

13.2. Sponsors (clinical trials) are required to submit a status report on the clinical trial to the licensing authority at the prescribed periodicity.

13.3. The IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research. Progress report of study should be submitted by investigator once in six months (for clinical trials) /one year (for other studies).

13.4. Investigators should ensure submission of the final report to IEC at the end of the study. Any protocol amendments, serious adverse events, unexpected events



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related to the study, and any event or information that may affect the benefit/risk ratio of the study, should be informed to IEC. Protocol deviations, if any, should be informed with adequate justifications. Serious adverse events from any site of the clinical trial should be forwarded to the ethics committee. This is the responsibility of both PI and sponsor.

13.5. Premature termination of the study shall be notified with reasons along with summary of the data obtained so far, by the investigator.

13.6. Change of investigators should be informed to the IEC.

13.7. Must inform the time of completion of the study and must send the result summary to IEC.

14. Special Considerations / Protection of Vulnerable Population:

There are certain specific concerns pertaining to specialized areas of research which require additional safe guards/protection and specific considerations for the DUPHMC-IEC to take note of. The DUPHMC-IEC gives special consideration and safe guards the interests of participants for research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy, and issues pertaining to commercialization of research and international collaboration. The observations of DUPHMC-IEC will be given in writing to investigators in such instances. Applicable guidelines will be used in decision making in such research studies.

15. Record Keeping and Archiving:

15.1. Record Keeping:

15.1.1. All documentation and communications of DUPHMC-IEC are dated, filed and preserved in a secure place. Only member secretary or persons who are authorized by chairperson will have access to records. Strict confidentiality is maintained during access and retrieval procedures.




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15.1.2. All active and inactive (closed files) are appropriately labeled and archived in designated areas

15.1.3. No document except agenda is retained by any IEC member

15.1.4. Following records are maintained in DUPHMC-IEC.

a) Administrative Documents:

- Constitution and Composition of the IEC.
- Curriculum vitae of all members with records of training.
- Consent Letters with confidentiality agreement.
- Conflict of interest declaration.
- Financial Records: all income and expenses of IEC, including allowances and reimbursement made to the EC members and secretariat.
- Registration documents.
- Regulatory notifications.
- A copy of the national and international guidelines and applicable regulations.
- Notices of meetings, minutes of meetings and other meeting-related documents.
- Standard operating Procedures.
- Copy of all correspondence with regulatory bodies.

b) Project Related Documents:

- One hard copy and one soft copy of initial research proposal and related documents.
- Decision letters.
- Any amendments submitted for review and approval.




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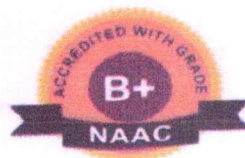
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- iv) Regulatory approvals.
- v) Reports and adverse events.
- vi) Progress reports.
- vii) Continuing review activities.
- viii) Review reports received from IEC members (full review, exempt review, expedited review).
- ix) All correspondence between the IEC and investigators
- x) Record of notification issued for premature termination of a study with a summary of the reasons.
- xi) Final report of the study.

15.2. Archiving: All documents will be archived for a period of 3 years after the completion /termination of the study. Documents pertaining to regulatory trials are archived for five years after the completion /termination of the study. Records will be archived for a longer period, if required by the sponsors/regulatory bodies.

Constitution and Composition of the IEC ; Curriculum Vitae and training records of all members ; Consent Letters with confidentiality agreement ; Conflict of interest declaration; Financial Records : all income and expenses of DUPHMC-IEC , including allowances and reimbursement made to the EC members and secretariat ; Notices of meetings, minutes of	Present committee and previous committees records to be available. For previous committees, the records to be archived for a period of five years after the completion /termination of ongoing clinical trials. For other research proposals, the records are to be maintained for 3 years.
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meetings and other meeting-related documents	
Registration documents	Present and the immediate previous
Copies of all correspondence with regulatory bodies	No defined period; all correspondence from first time formation of DUPHMC-IEC
Project related documents	for a period of five years after the completion /termination of ongoing clinical trials. For other research proposals, the records are to be maintained for 3 years.
Review reports of individual members	Upto One year after review

At the end of each meeting, every member will return the CD/hard copy/any other form of soft copy of proposals and documents to IEC office. One office copy will be archived and other copies will be destroyed after one month.

16. Dr. Ulhas Patil Homoeopathic Medical College And Hospital - Institutional Ethics Committee Fee structure: DUPHMC-IEC charges for the clinical trials as per following details.

The DUPHMC-IEC fee has been revised with effect from 1st January 2026, the details of the fee structure is as follows.	
1. Initial Review of study documents: (Protocol, ICF and other study documents)	
A. International Studies:	20,000.00
B. Indian Studies :	10,000.00
2. Expedited Reviews: (Protocol, other study documents)	
A. International Studies:	30,000.00
B. Indian Studies:	15,000.00



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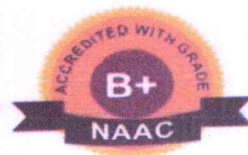
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3. Continued Reviews: (Review of any other study related documents submitted after initial review, eg: ICFs, Subject diaries, Dosing cards, Investigators brochure etc.

A) Protocol Amendments and other changes to the Study related documents:
3000.00

B) Review of Advertisements (Submitted subsequently initial review): 2000.00

4. Expedited Continued Reviews: (Review of any other study related documents submitted after initial review, eg: ICFs, Subject diaries, Dosing cards, Investigators brochure etc. 4000.00

5. Serious Adverse Events Reports : Not charged



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Annexures

Annexure -1:

Consent Letter from Members

DUPHMC Institutional Ethics Committee – Consent Letter from Appointed Member

To:

Dr. Ulhas Patil Homoeopathic Medical College and Hospital,
Jalgaon.

Sub : Consent to be the member of DUPHMC Institutional Ethics Committee.

Ref : Your letter No.-----; Dated -----

Dear Sir, In response to your letter, I give my consent to be the member of DUPHMC Institutional Ethics Committee. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential.

Thanking You,

Yours Sincerely,

Signature : Name :

Designation and Department/Affiliations :

Date :

Place :




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Annexure-2:

DUPHMC Institutional Ethics Committee Appointment Letter

To,

Sub : Appointment as member of Dr. Ulhas Patil Homoeopathic Medical College & Hospital Institutional Ethics Committee.

Dear Sir/Madam,

I am pleased to select you as a member of DUPHMC Institutional Ethics Committee with effect from ----- . As a member of the committee, you will have a tenure of three years. Conditions of appointment, and Responsibilities:

- 1) You should be willing to submit a recent signed curriculum vitae, training certificates on research ethics and good clinical practice guidelines as required
- 2) You should have the willingness to undergo training on research ethics and good clinical practice guidelines (if not trained already), and submit training certificates to the ethics committee
- 3) Be willing to place your full name, profession and affiliation to the ethics committee in the public domain
- 4) Review the research proposals, and attend ethics committee meetings ; to participate in discussions and deliberations
- 5) Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings
- 6) Shall not keep any literature or study related documents with me after the discussion and final review
- 7) To read, understand, accept and follow the conflict of interest policy of ethics committee , and declare conflict of interest if any at appropriate time.
- 8) Willing to undergo training or update programmes on relevant guidelines and regulations, research ethics ,and good clinical practice during the tenure as ethics committee member
- 9) Carry out monitoring visits at study sites as and when needed.
- 10) Review serious adverse event reports and recommend appropriate actions
- 11) Review the progress reports and final reports of research projects cleared by the committee



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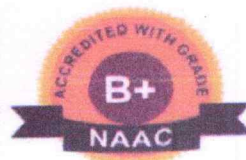
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12) As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC.

13) One month notice on either side will be necessary prior to resignation/termination of appointment.

For more details, kindly refer to the SOP of IEC which will be provided to you.

Annexure-3:

Guidelines for Submission of Research Proposals

1. Research proposals for consideration by DUPHMC-IEC should be submitted in 12 hard copies and one soft to office of DUPHMC-IEC.
2. The committee meets second Saturday of every month at 10.00am to 4.00pm. Depending on the load of research proposals, the frequency of meeting may be increased.
3. The proposals from DUPHMC should be approved by Research Committee, and after the approval, the latest corrected version of the research proposal should be submitted to ethics committee.
4. The research proposal should be accompanied by other documents (budget form, patient information sheet, informed consent form, undertaking, questionnaire, proforma of data collection) as applicable to the study.
5. For case reports, a copy of the informed consent form signed by the patient should be submitted to DUPHMC-IEC, along with a copy of the abstract and findings in the case study.
6. The research proposals will be categorized for review as: exempt review, expedited review and full committee review.
7. For the proposals categorized for full review, the principal investigator will be asked to present the proposal in the ethics committee meeting.
8. Principal investigator should be available for presentation of the proposal in the meeting in case of full committee review. Co investigators may accompany the principal investigator. Under no circumstances principal investigator will be exempted from presentation except in extraordinary circumstances. Chairman of DUPHMC-IEC will decide on this matter.
9. Research proposals are sent to members of DUPHMC-IEC for review atleast a week before the meeting. Investigators should keep this in mind while submitting proposals to DUPHMC-IEC. DUPHMC-IEC considers only 30 proposals for presentation in one meeting.
10. Decision of the committee will be communicated to principal investigator within two working days after the meeting.
11. Research proposals "approved" / "approved with suggestions" are permitted to start the work. Research proposals for "resubmission" need to revise the proposals and resubmit the proposals. For "Rejected" proposals, whole process of submission should be repeated considering the reasons for rejection




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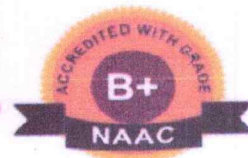
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12. If the ethics committee asks the investigators to do CTIR registration, it should be done and CTIR.no. should be communicated to the committee .

13. Ethical clearance is initially issued for one year; after one year the investigator has to request for continuation of ethical approval.

14. Ethics committee has every right to monitor the research study at any point of study duration.

15. The principal investigator should submit a report on progress of the study. Progress report should be submitted every six months (for clinical trials) or one year (for other studies). After completion of the project, final report should be submitted.

3A. Format for Submission of Research Proposals

1. Title of the Research Proposal :

2. Principal Investigator :

- 1) Name :
- 2) Designation :
- 3) Contact Address :
- 4) Contact Phone No. :
- 5) E mail ID :

3. Co Investigator /Co investigators :

Co investigator :

- 1) Name :
- 2) Designation :
- 3) Contact Address :
- 4) Contact Phone No. :
- 5) E mail ID :

If there are more than 1 co investigators, give same details as above.

4. Duration of the Study :

5. Type of Research Study : Staff project/ STSH project / Interns project/ UG project



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6. Description of the Study : Enclose the proposal copy

1) Introduction and Need of the study

2) Review of Literature

3) Objectives

4) Materials and Methods (source of data; study design; sample size; methodology in detail; statistical analysis)

5) Implications of the Study

6) Bibliography

7. Details of Budget :

1) Total Budget :

2) Grant in aid requested : Rupees -----

3) Funding Agency :

Enclose the Budget form 8 . Patient Information sheet and Informed Consent Form to be enclosed 9. Checklist of Documents to be submitted: 12 sets of the documents mentioned below --- Document	Tick if submitted
1) Covering letter from Principal Investigator	
2) Research proposal	
3) Budget form	
4) Patient information sheet and informed consent form	
5) Declaration from the Principal investigator about confidentiality of patient data (in case of retrospective studies)	
6) Data Collection proforma	
7) Questionnaire	
8) Any other formats / checklists used in the study	




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Annexure -4:

Format for Patient Information Sheet and Informed Consent Form

Title of the Study :

Names of Researchers/Investigators :

Name of Organization :

Name of Sponsor (Grant agency):

PART I: Information Sheet State your affiliations , explanation about the importance and objectives of the study, methodology in an understandable, simple language. If you are using any interventions/questionnaire/collecting information in a proforma/collecting any samples from the subject, mention it clearly. If you are doing any experiments/assays with the sample collected, mention them. How many times the samples or data will be collected from the subject –mention it. Also mention how the subject is selected (random sampling/purposive sampling, etc...). If you are using any new procedures ,this need to be mentioned .Possible side effects/risk need to be mentioned . What are the benefits to the subject from his/her participation in the research ? mention .If there are no direct benefits, mention what way his/her participation will benefit to the society as a whole . Duration of the study has to be mentioned. Confidentiality of data/information collected from the subject ? – make a statement about this. (Example. We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it) Whom to contact ? Provide the contact number and address of the researchers Mention that –This research project is reviewed and approved by Ethics Committee of DR. ULHAS PATIL HOMOEOPATHIC MEDICAL COLLEGE AND HOSPITAL, JALGAON. This is a committee whose task it is to make sure that research participants are protected from harm. The contact details of ethics committee are as follows:




Dr. Rakesh Kumar Mishra
Principal
Dr. Ulhas Patil Homoeopathic Medical
College & Hospital, Jalgaon Kh.



Godavari Foundation's

Dr. Ulhas Patil Homoeopathic Medical College and Hospital, Jalgaon Kh.

N.H. No. 6, Jalgaon-Bhusawal Road, Jalgaon (Kh.)-425 309, Jalgaon (M.S.)

Tel. No.: 0257 - 2366888, Fax No.: 0257 - 2366648

Email Id : duphmcj@gmail.com Website : www.duphmc.ac.in



- National Assessment & Accreditation Council (NAAC) with B+ Grade. ■ Quality Council of India (QCI).
■ UGC recognition of Colleges under section 2(f) of the UGC Act 1956. ■ ISO 9001:2015.

INFORMED CONSENT

I have read and understood the information/ it has been read to me and explained in an understandable language about the research project : -----(title). I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If illiterate A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be done: I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____



Dr. Rakesh Kumar Mishra
Principal
Dr. Ulhas Patil Homoeopathic Medical
College & Hospital, Jalgaon Kh.



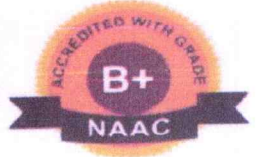
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Date _____ Day/month/year

Note : In case of children being the subjects of study ,the parents/guardian has to sign the informed consent form. This has to be mentioned clearly in the consent form as Name and signature of the parent/guardian. A statement in the end by the researcher should mention that the protocol was read out/explained to the parent/guardian of the child .

Consent form should be appropriately worded for adults and children (less than 18 years).

e.g. If the participant is less than 18 years of age, instead of „my participation“, „my child“/s/ward“/s participation“ needs to be replaced. In the information sheet, instead of you or your , mention :Your child“ or “your child“/s




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Annexure - 5:

Declaration By Principal Investigator on maintaining confidentiality of Patient Data (For Retrospective studies and Case Reports)

1. Title of the project:

2. Name, designation and department of the principal investigator:

I hereby give an undertaking that I will maintain the confidentiality of data collected from the case sheets / Hospital information system/ any other records of the hospital. While collecting the data, personal identity (name, address, contact number, e mail ID) of the patient will be concealed , and only the relevant data required for the study will be collected. For case report : The personal identity of the patient will not be revealed or made public. Photographs taken for study purpose will be used only for presentation or publication purpose. In the photographs, personal identity of the patient will be concealed . _____

Signature of PI Name _____ Date _____




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Indirect: Improvement in Any other science/knowledge

Subject selection :

i Inclusion / exclusion criteria addressed? Yes No

ii Vulnerable subjects (woman, child, mentally challenged,
seriously or terminally ill, foetus, economically or socially backward and healthy volunteers)
adequately protected ? Yes No

iii. Special group subjects (captives, students, nurses & Dependant staff) adequately protected?
Yes No

Privacy & Confidentiality maintained? Yes No

Patient Information Sheet: Adequate Inadequate

Consent form components addressed adequately? Yes /No

8. Compensation, (if applicable) addressed adequately? Yes/ No

9. Is there a Conflict of Interest? Yes /No

If yes, Acceptable Unacceptable

10. Budget: Appropriate Inappropriate

11. Decision of review Recommended/ Recommended with suggestions
/Revision /Rejected

Any other remarks/suggestions: Reviewer's name and Signature.



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Dr. Rakesh Kumar Mishra
Principal
Dr. Ulhas Patil Homoeopathic Medical
College & Hospital, Jalgaon Kh.



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You are instructed to register your trial in clinical registry (CTRI) before starting the study, and submit the necessary evidence to the IEC

Your research work will be continuously reviewed by ethics committee during the study period.

You are instructed to submit progress report of the research project once in every six months

You should comply with the regulations and guidelines on biomedical research on human participants, and follow good clinical practice

Ethics committee has the right to withdraw the approval if found necessary due to protocol violations, non-compliance to regulations and guidelines

For any modifications/changes in protocol, investigators and study site you need to submit the proposal to ethics committee and get the approval.

You should report any serious adverse events in your site or any other site of this clinical trial to the ethics committee

You need to submit the final report and summary at the termination of the study.

Following members of the IEC were present and involved in decision making. Name	Affiliations	Role in the Committee



Dr. Rakesh Kumar Mishra
Principal

Dr. Ulhas Patil Homoeopathic Medical
College & Hospital, Jalgaon Kh.



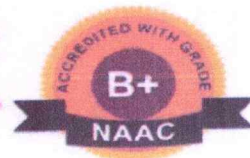
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Annexure 8:

Decision Letter Format (For studies other than clinical trials)

Ref. No. ----- Date :

Dear Dr./Ms/Mr. -----(Principal Investigator-name and address)

Your research proposal was discussed in the ethics committee meeting held on -----and the decision is as follows :

Protocol title: " "

Protocol No:

Principal Investigator:

Co Investigators :

Name & Address of Institution :

New review: Exempt review/ Expedited review/ Full review

Review of Revised Submission:

Date of review: Date of previous review, if revised application: Nil

Decision of the Ethics Committee: > Approved > Approved with suggestions > Revision/ Resubmission > Rejected

Suggestions /Reasons/Remarks:

Recommended for a period of : 1 Year

The approval is valid for one year. After one year, you are instructed to submit an application requesting for continuation of ethical clearance for another one year (if required).

Your research work will be continuously reviewed by ethics committee during the study period.

You are instructed to submit progress report of the research project annually

Ethics committee has the right to withdraw the approval if found necessary due to protocol violations, non-compliance to regulations and guidelines

For any modifications/changes in protocol, investigators and study site you need to submit the proposal to ethics committee and get the approval.

You need to submit the final report and summary at the termination of the study.

Following members of the IEC were present and were involved in decision making. Name	Affiliations	Role in the Committee



Dr. Rakesh Kumar Mishra
Principal
Dr. Ulhas Patil Homoeopathic Medical
College & Hospital, Jalgaon Kh.



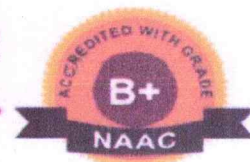
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Annexure 10:

Declaration of AI Usage

Have AI-based tools been used in the preparation of this submission?

Examples of AI-based tools include ChatGPT, Copilot, Deepseek, and Gemini.

Click the box that applies.

☐ Yes

☐ No

If yes, complete the rest of the declaration.

- In my work, I have used the following AI-based tools:

Examples of AI-based tool are Copilot, ChatGPT, Scopus AI, or others.

- I have used AI-based tools in the following way (max 300 words)

Signature of PI: _____




Dr. Rakesh Kumar Mishra
Principal
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