Institutional Ethics Committee

Dr . Ulhas Patil Medical College & Hospital Jalgaon Kh.

EC. Reg. No. ECR/825/INST/MH/2016

IEC, DUPMCH SOP

Designed by

IEC DUPMCH

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SOP version 3

	Name	Designation	Signature with date
Powered by	Dr. Rahul Prakash Bhavasar	Member secretory	29.10.21
Authorized by	Dr. Parag Ramchandra Patil	Chairman	29.10.21

Reviewed by

Name	Designation	Signature
Dr. Shubhangi D. Chaudhari	Member	
Dr. Vaishali Nagose	Member	
Dr. Shivaji Sadulwad	Member	
Dr. Nilesh Bendale	Member	
Adv. Satish Gadge	Member	
Dr. Prashant S. Warke	Member	
Prof. Girish A. Kulkarni	Member	
Mrs. Swara J. Waghodkar.	Member	

SOP MANUAL
INSTITUTIONAL ETHICS COMMITTEE, DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL, JALGAON KHURD, 425309

Standard Operating Procedures-Manual
SOP Title: Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd, Standard Operating Procedure (IEC, DUPMCH, SOP) SOP Authors: IEC, DUPMC, Members

SOP Status: Current
Version No and Date: 3 and Date: 28th Oct 2021 Validity: 3 year from the Date or till next revision Compiled by: Dr. Rahul Prakash Bhavasar, Member Secretary
Reviewed by: All committee members

Approved by: Chairperson: Dr. Parag Patil.
Fee Structure of Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd (IEC, DUPMCH)

Fees for Protocol Review and Approval:

Particulars	Fees (INR)
Submission for Clinical Trials for IEC review	75,000+GST
Submission of Amendments of Approved Protocols for IEC review	30,000+GST
Extraordinary Submission for Clinical Trial for expedited(fast-track) IEC review	1,00,000+GST
Extraordinary Submission of Amendments of Approved Protocols for expedited(fast-track) IEC review	60,000+GST
Annual Renewal of Clinical Trial Approval by IEC	25,000+GST
Submission for Serious Adverse Event for approved Clinical Trials	35,000+ GST

The IEC, DUPMCH reserves all rights to waive these fees or change this amount without any prior notice to anyone except the committee members.

Payee Name: DR. ULHAS PATIL MEDICAL COLLEGE

PANCARD NO – AAATG1840Q

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STANDARD OPERATING PROCEDURE (SOP) OF IEC, DUPMCH

Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital (IEC, DUPMCH) intends to review and oversee the conduct of biomedical and health research as well as clinical trial research. The IEC, DUPMCH is constituted in accordance with and ensures its compliance to the ethical guidelines of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, New Drugs and Clinical Trials Rules dated 19 March 2019, ICH-GCP, the Indian Council of Medical Research (ICMR) and functions in accordance with said guidelines and it is conducted in Dr. Ulhas Patil Medical College and Hospital, JALGAON and all constituent colleges.

1. OBJECTIVE

The objective of Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital (hereinafter referred to "IEC, DUPMCH") of Dr. Ulhas Patil Medical College and Hospital (hereinafter referred to "DUPMCH") is to

1. Ensure ethical review of research protocol and the conduct of research at DUPMCH affiliated institutes which involves human participation.
2. Safeguard the safety, dignity, and welfare, including privacy and confidentiality, of the participants involved in the research study directly or indirectly.
3. Ensure that all biomedical research are as per ethical guidelines
4. Provide periodic review of ethical decision taken for all research proposals to ensure the quality, consistency and its adherence to the applicable ethical guidelines.

2. AUTHORITY FOR CONSTITUTION OF ETHICS COMMITTEE

The DEAN, DUPMCH shall constitute the Institutional Ethics Committee, in consultation with the Director of DUPMCH, Registrar of DUPMCH, Chairperson and the Member Secretory of IEC, DUPMCH.

3. FUNCTIONS OF INSTITUTIONAL ETHICS COMMITTEE (IEC)

- To provide independent, comprehensive and timely reviews of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.
- IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding.
- The goals of research, however important, should never be permitted to override the health and well being of the research participants.
- The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, Non-malfeasance and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required.
- It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through final report and site visits if required.
- The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.
- The ethics committee should exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or other incapable of personally giving consent.
- Ethics committee should get documented "standard operating procedures" and should maintain a record of its proceedings.

- Ethics committee should indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licensing Authority.
- Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licensing Authority.

4. HUMAN RESEARCH REVIEW PANEL (HRRP) CONSTITUTED UNDER IEC, DUPMCH AND ITS PURVIEW

IEC, DUPMCH is considered as the apex body for ethical aspect of research serving to following FOUR constituent Institutes of Godavari Foundation.

A. Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd
B. Godavari College of Nursing
C. Dr. Ulhas Patil College of Physiotherapy
D. Dr. Ulhas Patil Homeopathic Medical College and Hospital

The IEC has constituted Human Research Review Panels (HRRP) at each constituent college/department, which will facilitate the functioning of IEC. The HRRP will function as the first window for accepting applications of all Biomedical and Health Research synopses in the prescribed format (Refer Annexure 1) except for the clinical trial synopsis (protocols) which will be accepted directly at the IEC, DUPMCH secretariat office.

HRRP will review the submitted proposals and provide its comments to IEC, DUPMCH. The HRRP will also facilitate the IEC, DUPMCH by giving their opinion on the level of risk of the submitted protocols; comments on the submitted synopses, give a regular follow-up report on the ongoing studies and all submission related documents will be filed by the HRRP office for records.

HRRP shall consist of 4 to 20 members of respective college experts. They will review both the students' "and faculties' "research projects. Those research studies which involve the new drug or technology use, new indication, company sponsored trials; PhD studies etc will be discussed in full board ethics committee meeting only. In case of studies involving high risk, HRRP will forward it to IEC, DUPMCH after due technical review and along with comments for full board ethics committee review.

The HRRP will not, in any form, give any approvals or certificates with respect to the research submissions.

5. PROTOCOL FOR UPDATION OF STANDARD OPERATING PROCEDURE:

The SOP covers the procedure of writing, reviewing, distributing and amending SOPs within the IEC, DUPMCH. The IEC, DUPMCH updates its own Standard Operating Procedures based on applicable regulatory guidelines.

a. Amendment Requestor Preparation of New SOP:

IEC, DUPMCH updates SOP, whenever new Regulations or any Amendments from Central Regulatory Board have been received, any member of the IEC, Secretariat, administrative staff, investigator or authority can make a request for revision or on noticing an inconsistency/discrepancy or has any suggestions can put forth his/her request by using the request application (Refer Annexure2).

Among any of the above Mentioned case, discussion shall be done amongst the IEC, DUPMCH members in meeting. Upon agreeing of the members to this request, Chairman will appoint a SOP Subcommittee for the changes in the SOP as per requisition. If majority of IEC members do not agree to the request, no further action will be taken. Chairperson will inform the member who made the request in writing about the decision. In any case, final decision whether or not to form the subcommittee will be of the Chairperson.

b. SOP Subcommittee

The Chairperson will establish an SOP subcommittee having thorough knowledge about the scientific and ethical review process which includes member secretary, 1 or 2 member and administrative staff. SOP team may carry out writing the procedure of IEC or make the changes requested. The draft SOP will be formulated by SOP team.

c. Review of the draft SOP and submission of final draft SOP

The Draft SOP will be reviewed by the all EC members. If any comment or suggestion will be incorporated and final approval will be taken in EC meeting.

d. Approval of New / Revised SOP

The Final SOP will be signed by Member Secretary and Chairperson IEC, DUPMCH, which then will be forwarded to authority of the DUPMCH and regulatory authorities. The date of approval is the effective date of implementing the SOP.

e. Implementation, Distribution and Filing of the SOPs

The date of approval is the effective date of implementing the SOP. The Approved SOPs will be notified to the licensing authority of India. These SOPs will be circulated amongst the member of the EC, administrative staff, DUPMCH authority, HRRPs of respective institutes and the Investigators. A log will be maintained for the recipient of SOP by IEC, DUPMCH office. The

Original Set of the SOP will be maintained in the SOP master file for record. The paper photocopies of the same will be valid for official use, only with the dated signature of the member secretary.

f. Manage and Archive Previous Versions of SOPs

Previous versions of SOPs will be retained and clearly marked "Superseded" and archived in a file by the Member Secretary/Administrative staff at the archival room of the IEC, DUPMCH.

6. COMPOSITION OF IEC, DUPMCH

The Purpose of IEC, DUPMCH is to have uniformity in the Ethical Review process and to critically analyze the Scientific and Ethical concerns associated with the research submissions in either of these forms:

1. Post Graduate Dissertations/research studies
2. UG Student Research Project
3. Faculty Research Projects
4. Sponsored Clinical Trial Protocols.
5. Any other biomedical and health research involving human participants

IEC, DUPMCHs shall be multi disciplinary and multi-sectoral in composition. The number of members in the committee shall be at least 7. The external members shall be present to ensure the independence of the committee. The Chairperson of the committee shall be from outside and non- affiliated with the Institution. Moreover, The Co-Chairperson (Co-chair) would be appointed which would act as decision authority in absence of the Chairperson. She/he shall also not be affiliated with the institution.

The Member Secretary shall be nominated from the members of the DUPMCH itself. The member secretary shall conduct the administrative duties of the ethics committee. Other members will represent different specialties from medical and non-medical background to reflect the different viewpoints. The composition of the IEC, DUPMCH shall be as follows,

1. Chairperson (Non Affiliated with the DUPMCH)
2. Basic medical scientist/Scientists
3. Clinician/Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Layperson from the community(Non-affiliated with the DUPMCH)
7. Member-Secretary (Drawn from the Institute)

IEC, DUPMCH shall also have members from other institutions from constitutional institutes of DUPMCH. There shall be an adequate representation of age, gender, community etc. in the committee to safeguard the interests and welfare of all sections of the society. The Committee shall have at least one women representation. (Refer Annexure 3 for updated IEC, DUPMCH composition). The Ethics Committee referred consists of at least fifty percent of its members who are not affiliated with the institute or organization.

a) Independent Consultants

IEC, DUPMCH will call upon Subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. Subject experts shall not have voting rights. Confidentiality agreement (Refer Annexure 4) must be signed by them regarding the meeting and the protocols deliberations.

b) Secretariat

The Secretariat consists of the Member Secretary and administrative staff/support staff. The administrative staff shall be appointed by the institute as per university rules and regulations.

c) Membership

The DEAN, DUPMCH will appoint the Chairperson, IEC and the member Secretary in consultation with DIRECTOR, DUPMCH. All the members of IEC will be appointed by the Dean in consultation with the Chairperson and member Secretary. CV of all members will be collected in a single format. (Refer Annexure 5) IEC, DUPMCH will inform to licensing authority of India about the constitution of IEC or about the changes in membership list if any.

d) Appointment

The selection of EC member shall be based on the qualification and experience, Ethical & Scientific knowledge, Interest, Commitment & availability, willingness to provide unbiased opinion etc. Members representing as medical Scientist or clinician should have post graduate qualification and adequate experience in their respective field. There should not be any conflict of interest while making an appointment. Directors, Head of Institutions, Superintendents and authority of university will not serve as a member.

e) Terms of Office, Renewal, Resignation or Termination of membership

The duration of the membership will be for a minimum of period of 5 years. The membership shall be renewed after the stated term. There will be no bar on the members serving for more than one term but it is desirable to have around one third new members during the reconstitution. A member who wishes to resign should provide a written notification of their proposed resignation date to the Chairperson of IEC, DUPMCH or Dean, DUPMCH. A new member can be appointed of the same category (For e.g. If Legal advisor resigns then the new legal expert

should be appointed) by the Dean, DUPMCH in consultation with Chairperson and Member Secretary.

A member can be replaced in the event of long-term non- availability (three consecutive meetings). Letter of Termination will be provided to the member. Authority to replace the member shall remain with the Chairperson of IEC, DUPMCH. University authorities shall be informed about this termination and it should be documented in the minutes of next duly constituted IEC meeting.

Any changes in terms of membership i.e. Resignation/Termination shall be notified in written to the licensing Authority of India.

f) Roles and Responsibilities of IEC, DUPMCH

The Prime responsibility of IEC, DUPMCH is to determine the Scientific and ethical aspects of Research Proposals and ensuring the protection of rights, safety and well being of the research participants. The committee shall;

- Provide independent and competent review of all ethical aspects of research proposals within stipulated time frame.
- Ensure to safeguard the dignity, rights, safety and well being of all study participants. Special consideration to be ensured in reviewing the protocols involving vulnerable population.
- Scientific aspects of the research proposal shall be evaluated.
- Review progress report and monitor ongoing studies.
- Evaluate the suitability of the Investigator in terms of qualification, training and experience as documented in CV for the proposed study.
- Review and revise SOP from time to time as per SOP.
- Maintain confidentiality of the study documents and deliberation of the IEC meeting.
- Monitor SAEs, protocol deviations & violations and recommend appropriate actions.

- Shall actively participate in educational training program and remain trained & updated on the regulatory requirement.

Chairperson will be responsible for

- Chairing the meeting and accountable for independent and efficient functioning of the committee
- Seeking Conflict of Interest (CoI) declaration from members and ensure quorum and fair decision making.
- Ensuring active participation of all members in all discussion and deliberations.
- Appointing new members and forming subcommittees for any task.
- Facilitating IEC educational activities and keeping abreast the regulation and policies governing review of research projects involving human subjects.
- Handling of complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Member Secretary and the Secretariat will be responsible for the following

- Effective and Streamlined process of receipt, preparation, circulation and handling of each proposal for review.
- Arranging/Scheduling IEC, DUPMCH meetings on regular basis(once in three months and/or as and when required)
- Communication of IEC members with Investigators, Chairperson and with Regulatory Authority
- SOP update as and when required.
- Completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Review and Recommendations for expedited review/ exemption from review or full review of submitted synopses/protocols.
- Maintaining the financial records of IEC.
- Making pre and post arrangements of IEC meeting.

- Assess the need and recommendations to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions taken in form of minutes.
- Filing study related documents i.e., Archiving and maintaining the study files.

`Other IEC, DUPMCH Members` will represent appropriate balance of professional, ethical, legal, cultural, clinical and community interest. Their Primary responsibility will be of determining the Scientific and Ethical Validity of the research and the protection of the safety, rights, well being & confidentiality of the research subject.

`Basic Medical Scientist` will be preferably a pharmacologist as IEC, DUPMCH reviews clinical trials with drugs as well as biomedical and health research involving human participants and will be responsible for:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, biomedical and health research involving human participants, pharmacologist to review the drug safety and pharmacodynamics.

`The Clinician` will be an individual with recognized medical qualification, expertise and training and will be responsible for

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

- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

`The Legal Expert` will be an individual having basic degree in law from a recognized university, with experience.

- He/she will be involved in ethical review of proposal, ICD along with translations, MoU (Memorandum of Understanding), Clinical Trial Agreement (CTA), regulatory approval, Insurance document, other site approvals, researcher's undertaking, protocol specific other permission if any.
- `The Social Scientist` will be any individual with social/ behavioural science /philosophy /religious qualification and training and/or expertise and be sensitive to local cultural and moral values. She/he may be from an NGO involved in health-related activities
- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal /community representative and bring in ethical and societal concerns.

`The Lay person` can be any literate person from the public or community has not pursued a medical science/ health related career in the last 5 year and is aware of the local language, cultural and moral values of the community. She/he shall be responsible for:

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

g) Training

Training on the ethical aspects of health-related research with human participants and on the IEC, DUPMCH SOP shall be imparted to the IEC members when they join and periodically during their committee service. Member secretary shall be responsible for providing training to the new members.

The revised/amended IEC, DUPMCH SOP training shall be given by the member secretary/other member of the SOP team to rest of the IEC Members before the new IEC, DUPMCH SOP comes into enforcement. The IEC shall conduct workshops from time to time to impart training to the IEC members and Institutional faculty members.

h) Conflict of Interest and Confidentiality

- It shall be declared by the IEC, DUPMCH members at the first meeting that there is no direct conflict of interest, possible conflicts of interest that may compromise his/her position on the IEC by signing the conflict of interest (CoI) form (Refer Annexure 6). If a member has direct conflict of interest with a proposal being considered shall not be a part of the quorum.
- There should not be any undue influence of the members by the way of their institution association, financial liability, kinship or authority in their decision.
- The member having conflict of interest with any of the proposals for review in the meeting will disclose it before the meeting and will fill the Conflict of Interest Disclosure Form (Refer Annexure15).
- All the IEC, DUPMCH members should maintain absolute confidentiality of all discussions during the Meeting, including the documents circulated for review, unless required by law.
- It is responsibility of each IEC, DUPMCH member to read, understand, accept and sign the Confidentiality Agreement (Refer Annexure 6) regarding meeting deliberations, applications, information on research participants and

- related matters at the beginning of the tenure of his/her membership and the term of which shall be binding on them even after the termination of the contract.
- These signed confidentiality and conflict of interest forms will be filed in a separate file by IEC, DUPMCH secretariat.

i) Quorum Requirement for Meeting

The full board meeting will be held as scheduled for clinical trial review provided there is quorum. A minimum of 5 members shall be required for a quorum representing the following background:

- Basic Medical scientist(preferably a pharmacologist)
- Clinician
- Legal expert
- Layperson
- Social scientist or representative of Non-governmental voluntary agency
  All decisions shall be taken in meetings and not by circulation of project proposals.

j) Schedule of Meeting

IEC, DUPMCH shall meet regularly at least once in three months; however, the frequency of IEC meeting shall be based on the number and the type of protocols eg. Clinical trial or Biomedical and health research to be reviewed.

k) Honorarium to the Members/Independent Consultants

Honorarium for attending IEC, DUPMCH meetings shall be given to the IEC, DUPMCH members as per financial policy of IEC, DUPMCH. Reimbursement of travelling expense and/or honoraria may be given to Independent consultant and any other person authorized by the IEC, DUPMCH.

1) Evaluation of IEC/Chairperson/Member Secretary/Members/IEC Staff- Self- assessment

The committee will carry out periodic self-assessment once a year.

The member/s and administrative staff will be designated by Chairpersons for carrying out self assessment. The corrective and preventive actions (as required) will be discussed in the full board meeting and will be implemented accordingly (Refer Annexure 16) Annual Self Evaluation of Chairperson will be done.

Annual Evaluation of IEC, DUPMCH members/ Member Secretary will be done by Chairperson. The individual feedback will be provided by email to the members.

7. ADMINISTRATIVE SUPPORT:

To support the smooth functioning of the IEC, DUPMCH, the administrative staff shall be appointed by the Head of the Institute. The Secretariat of IEC, DUPMCH includes the Member Secretary of IEC, DUPMCH and the support staff.

IEC, DUPMCH makes certain that the support staff is adequate in numbers and trained enough to enable the IEC, DUPMCH to carry out its technical and administrative responsibilities.

Adequate resources will be provided to support staff to fulfill its assigned functions including office space, and equipment and supplies. (e.g. computers, stationery, telephones, photocopies, shredding machine etc.)

The supporting staff will assist the member secretary in executing functions of the IEC and it consists of the staff members of DUPMCH appointed by the DEAN of DUPMCH. Additional supporting staff may be appointed as per requirement after discussion amongst the IEC, DUPMCH members.

Duties of the Administrative Staff:

- Establish an effective and smooth handling procedure for each proposal received at IEC, DUPMCH Secretariat. This includes its receipt; register entry, circulation for further review and storage management.
- Assisting Member secretary in organizing IEC, DUPMCH meetings regularly, in preparation of the agenda and minutes of meetings.
- Maintaining IEC, DUPMCH records and archives.
- Communicating with IEC, DUPMCH members and Principal Investigator.
- Assisting Member Secretary in arranging training for Faculty, PG students of DUPMCH and IEC, DUPMCH members.
- Providing necessary administrative support for IEC, DUPMCH related activities to the Member Secretary, IEC, DUPMCH.
- Receiving IEC, DUPMCH processing fees and forwarding to Account Department of DUPMCH and receiving and maintaining official receipts for the same.
- Corresponding with the IEC, DUPMCH members, external experts and investigators.
- Making the pre and post arrangements of IEC, DUPMCH meetings.
- Filing study related documents.
- Assisting in preparation for accreditation and audits of IEC, DUPMCH
- Participate in the development and subsequent implementation of SOPs

All the communications between the IEC and Investigator/Institution/Regulatory Authority will be from and through the member Secretary/Chairperson of IEC, DUPMCH.

The Secretariat of IEC, DUPMCH will receive protocols for review/notification/request from Students, Faculties and Principal Investigator of DUPMCH and then will circulate amongst the IEC, DUPMCH members.

Any Decision made regarding the study (Approval/Rejection/Query response requested) shall be communicated from Member Secretary on behalf IEC, DUPMCH to the respected applicant/applicants.

Correspondence Regulatory agencies will be carried out through Chairperson/Member Secretary of the IEC, DUPMCH.

8. APPLICATION PROCEDURE

For Biomedical and Health Research:

The following procedure will be followed by the Students and Faculties of DUPMCH for submission of the Research Proposals.

- Research Proposals along with the relevant documents shall be submitted along with an Application Form in the prescribed format (Refer Annexure 1) and addressed to Chairperson/Member Secretary of IEC, DUPMCH.
- The Application shall first be addressed to the HRRP (Human Research Review Panel) Coordinator of the concerned college/department of DUPMCH which will serve as a first window for accepting all the research proposals from students/faculties of their college/department. HRRP will acknowledge the receipt and indicate any lacunae. Re-submission in case of missing information/clarification requested shall be done within two weeks.
- The HRRP will Review the Research Proposal and shall provide their Opinion/Comments and then forward the same to member secretary of IEC, DUPMCH.
- The IEC, DUPMCH will acknowledge the receipt of the application with supporting annexure.
- IEC, DUPMCH shall review the Research Proposal received and then either Approves/Rejects the Proposal or raises the queries to the Investigator. The decision of the IEC, DUPMCH shall then be communicated through HRRP to the applicant in writing.

For Clinical Research:

- All the Research Proposal shall be addressed to the Chairperson of the IEC, DUPMCH, and shall be submitted to the Member Secretary/Secretariat.
- Member Secretary/Secretariat will ensure the completeness of the submission against the checklist for Clinical Trial Documents and to IEC, DUPMCH (Refer Annexure 17) and then will provide the applicant, the acknowledgement receipt (Signed, Stamped and dated) for the submitted documents.
- In case of incomplete submission or in case if additional documents required, member secretary will inform PI to re-submit missing document or to submit additional document required. Member Secretary will reconfirm the completeness with the prior submission and updates the submission accordingly.
- Total 10 hard copies and One(1) soft copy of the study documents shall be submitted to the IEC, DUPMCH. The number of hardcopies to be submitted may vary depending on number of members in EC constitution.
- Application shall be made along with the prescribed fees for the review of proposal. (New Protocol/Amendment/Expedited Review)
- As per IEC, DUPMCH, the Fees will be accepted as cheque /demand draft drawn in favor of "DR. ULHAS PATIL MEDICAL COLLEGE".
- A unique submission number shall be assigned to each proposal submitted for review.
- Submission shall be done at minimum 3 weeks prior to the next IEC, DUPMCH meeting.
- Investigator shall be notified in writing to be present for a scheduled IEC, DUPMCH meeting to present their protocol and offer clarification if any required during the meeting.
- In case of any Amendment PI should submit one (1) hard copy of the amended documents highlighting the modification/s in the amendment along with summary of changes. The member secretary in consultation with Chairperson will decide whether to carry out Expedited Review or request Notification in case minor administrative changes.

- In case of requirement of full board review, PI should submit 10 hard copies of the amended documents along with the prescribed EC fees to IEC, DUPMCH.

9. ESSENTIAL DOCUMENTS TO BE SUBMITTED FOR REVIEW

All research proposals including clinical trials shall be submitted minimum 3 weeks before the upcoming IEC, DUPMCH meeting with the following documents.

I. Documentation Required For Biomedical and health Research:

- Cover letter to Member Secretary
- Application Form (Annexure – 1)
- Title of the project (Cover Page -Title of the Proposal, Name & Sign of the PI and Co-I with Designation, Name of any other Institute/Hospital/Field area where research will be conducted)
- Names of the PI and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Approval of the Head of the Department.
- Protocol of the proposed research
- Ethical issues in the study and proposed measures to address these issues.
- Proposal shall be submitted with all relevant Annexure like proforma, Case Record Forms, Questionnaires, follow-up cards, etc. to be used in the study.
- Participant Information Sheet and Informed Consent Form in vernacular language(s) should be enclosed. The consent form shall be as per new drugs and CT rules2019.
- For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.

- Any regulatory clearances required. Copy of clearances if obtained. This will be necessary for New drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
- Source of funding and budget along with the supporting documents.
- Indemnity issues including insurance certificate for the compensation to the participants etc, if applicable.
- Statement of conflicts of interest, if any.
- Plans for publication of results-positive or negative-while maintaining the privacy and Confidentiality of the study participants.
- Any other information relevant to the study.

II. Minimum documentation required for Clinical Trials

Ten (10) sets of hard copy and one (1) soft copy of the following documents have to be submitted along with continuous pagination i.e. for every new document, corresponding page numbering should start from where it ended for the previous document and not as page no. one (1).

a) Cover letter to Member Secretary
b) Final Version of Protocol of the proposed research.
c) Investigator Brochure (IB) (as applicable for drug/biological/clinical trials)
d) The Final Version of Patient Information Sheet (PIS) and Informed Consent Form (ICF) in English, Hindi and Marathi along with a translation certificate and Back translation certificate wherever applicable.
e) Final Version of Case Record Form(CRF)
f) Recruitment Procedure; advertisement, notices (if applicable)
g) Patient Instruction card, diary, etc. (if applicable)

h) Insurance Certificate for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage risk or Indemnification policy document (if applicable).
i) Acknowledgement and/or Permission letter from licensing authority to conduct clinical trial
j) Any other regulatory permissions(As applicable)
k) Final Version of Clinical Trial Agreement (CTA)/Clinical Study Agreement (CSA)
l) Undertaking by the Investigator
m) Principal Investigator's current CV, MRC and GCP training certificate duly signed and dated.
n) Clinical Trial Registry – India (CTRI) Registration Certificate

10. REVIEW OF PROPOSAL

The member secretary shall screen the proposal for the risk associated with the study depending upon the risk, as defined in "New Drugs and Clinical Trial Rules 2019" involved in the research proposal, the member secretary shall subject them to: Full Board Review, Expedited Review and Exemption from Review.

All research involving the following will be subjected to Full Board Review:

- Research involving more than minimal risk.
- Proposals/Protocols which do not qualify for exempted or expedited review.
- Projects involving vulnerable population such as children, prisoners, pregnant women, mentally disabled persons, or other special groups.

The foremost task of the IEC is to review the study proposal and supporting documents giving importance to its scientific validity, ethical issues and submission form for suitability and feasibility of the study. The IEC, DUPMCH will analyze and take into the consideration the following criteria to ensure the ethical basis of review of the submitted protocol.

1. Risk Factors, Adequacy against Risks & Potential Benefits:

It should be taken care that the subject participating in the research that bear the risk of participation shall be benefited out of research directly or out of new knowledge that the research is designed to yield. IEC members should be aware that risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration.

IEC, DUPMCH Members shall ensure that Research is scientifically sound and valid because if the research is not scientifically valid then it exposes research participants and their communities to risks or harm without possibility of benefit.

2. Recruitment & Withdrawal of Subject(s):

Recruitment strategies shall describe the purpose of the research, the risk and potential benefits of participating in the research and other relevant details. Patient's participation in the study should be voluntarily. It has to be checked there is no influencing factor for the patient's participation in the study. It is to be ensured that patient can willingly withdraw the consent with prior intimation. This should not affect his/her further routine medical treatment.

3. Access to personal data:

Access of personal data of the research participants, including medical records, source data and biological samples shall remain with the Principal Investigator and supporting Staff. With Permission of the PI, the regulatory authorities/Ethics committee can have access to these data for Audit/Monitoring purpose.

4.Investigator's Qualification:

IEC, DUPMCH shall ensure the required qualification and experience of the investigators and adequacy of the site for the proposed study.

5. Data and Safety Monitoring for the Clinical Trials and biomedical and health research:

IEC, DUPMCH will monitor the ongoing studies at site continually for ensuring compliance to study protocol. This includes review of the overall progress of each study to insure safety of the study participants, validity of the data, evaluating the risks and adverse events, reporting of the adverse events to the appropriate agencies. IEC, DUPMCH shall make a visit in case of reporting of adverse events or violation of human rights.

6. Financial benefits and Costs to Research Subjects:

Subject shall be reimbursed for any cost associated with participation in the study, including transportation, child care or lost wages. However, the payments shall not be high enough that will eventually influence the subject to participate in the research.

7. Serious Adverse Events Monitoring:

IEC, DUPMCH ensures the provisions are made for compensation/treatment and reporting of the events done by Investigator in the case of injury/disability/death of a research participants as per existing national legislation (CDSCO).

8. Complaint/Query by the Research Participants:

Member Secretary/Administrative staff upon receipt of the query/complaint records it in a register and informs the Chairperson. Chairperson along with member secretary will investigate the details to determine the truth and individual perception. Chairperson may even be able to consider the matter for full board review and appoint a sub-committee for enquiry. The final decision shall be informed to research participants by the secretariat.

Elements of Review are further described in this SOP.

11. EXPEDITED REVIEW AND EXEMPTION FROM FULL REVIEW EXPEDITED REVIEW

Virtual or Tele/Video conference should be attempted to ensure social distancing as face-to-face meetings may not be suitable. Use virtual software platform (Zoom, google meet) preferably a video

National Guidelines For EC Reviewing Biomedical & Health Research During Covid -19 Pandemic ICMR APRIL 2020)

Proposals which are recommended for minor revisions will be reviewed by a subcommittee or Member Secretary for clearance and will be approved by the Chairperson/Member Secretary.

The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed in the next ethics committee meeting.

If Sponsor of Clinical Research intends Research Proposal (Initial/amendment) to be reviewed before 15 days then this will be considered as Extraordinary Submission and applicable fees will need to be paid for this fast track review process by the Sponsor.

EXEMPTION FROM FULL REVIEW

The criteria for exemption include those considered as “minimal risk” suggested by the ICMR Guidelines, 2017. Exemption from review may be granted to proposals which satisfy one of the following conditions:

Exemption 1: Research conducted in an established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement); survey/interview procedures; observation of public behavior,unless:

(i) Informationobtainedisrecordedinsuchamannerthathumansubjectscanbeidentified Directly or through identifiers linked to the subjects and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption 4: Research and demonstration projects that are conducted by or subject to the approval of heads of Government departments or agencies and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programmes (ii) procedures for obtaining benefits or services under those programmes (iii) possible changes in or alternatives to those programmes or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programmes.

* Research involving Vulnerable Population (For SOP for Vulnerable/Special Population – Refer Annexure 8) will not be considered for exemption from review.

Procedure for Exemption from Full Ethics Review:

It is the responsibility of PI to apply for research proposal for approval to HRRP. HRRP based on above criteria will take decision on "minimal risk" research proposal. The committee will recommend to IEC, DUPMCH for approval. The IEC, DUPMCH has empowered the member secretary to give approval to such research proposal. All such approvals shall be presented in next ethics committee for information to the committee.

12. AMENDMENTS TO PROTOCOL AND THEIR APPROVAL

Any proposed change or revision to IEC, DUPMCH approved study that affects human participants must be reviewed and approved by the IEC, DUPMCH prior to the implementation of that change. It is the responsibility of the Member Secretary/Chairperson to determine whether the proposed protocol amendment(s) is minor or major in nature. If there is minor amendment of the protocol and related documents, then it will be reviewed by member secretary/Chairperson.

Only administrative changes such as changes in telephone numbers; addition/deletion of staff or Investigators; changes in funding, alteration of the project title; typographical error in protocol, etc, do not require approvals, but they must be notified to IEC, DUPMCH.

For major amendment all the changes will be discussed in upcoming IEC, DUPMCH full board meeting.

A change which requires full ethics board review and approval is one which, in the judgment of the IEC reviewer, makes substantial alteration in:

- The level of risks to participants,
- The research design or methodology such as replacement of or significant changes to study instruments including surveys and questionnaires or adding/revising eligibility criteria or changes to the study population
- The number of participants enrolled in the research
- The informed consent to include a newly identified risk related to the study (this may require that participants sign a new consent form)
- The qualifications of the research team
- The facilities available to support safe conduct of the research
- In advertisement
- Addition or deletion of sites (due to non-recruitment or SAE, fraud and misconduct)
- Any other factor, which would warrant review of the proposed changes by the convened IEC. In addition, revised procedures must involve no more than minimal risk

The final decision regarding the amendments shall be informed to the Principal Investigator and the decision can be approved, approved with modification, or not approved.

The PI should highlight the modification/s in the amendment, along with summary of changes.

13. ELEMENTS OF REVIEW

The emphasis should be given on ethical guidance, grounded in the core principles of Respects for person, concern for welfare and justice. The foremost responsibility of the IEC is to review research proposals and their supporting documents with special attention to safety of the participants involved in research. The followings shall be taken into consideration during the review of a Protocol:

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks/harms and potential benefits.
- Procedure for selection of participants including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
- Management of research related injuries, adverse events and compensation provisions.
- Justification for placebo in control arm as well as Placebo arm in the study? If any.
- Availability of products to the trial participants after the study, if applicable.
- Patient information sheet (PIS) and informed consent form (ICF) in English/Hindi and local language
- Protection of privacy and confidentiality of participants.
- Involvement of the community, wherever necessary.
- Protocol and proforma of the study including the consent form (CF).
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure.

Review Checklist (ReferAnnexure9) will be filled by each IEC, DUPMCH member for each clinical trial proposal to be reviewed in the IEC, DUPMCH meeting.

Protocol

The Clinical Research Protocol should be as per New Drug and Clinical Trial Rules dated March 2019 (Refer Annexure 10)

Informed Consent Form and Participant Information Sheet

The IEC, DUPMCH will assess the adequacy of safeguard of the rights and welfare of the research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation criteria to ensure protection of the human subjects participating in the research is well defined in the Review of Proposal of this SOP.

Informed consent is most crucial element of research that needs to be taken care by every investigator participating in the research. “The Voluntary Consent of the human subject is absolutely essential as has been laid down in the Principle of the Nuremberg code. Obtaining consent from Research Participants involves both the consent dialogue and the documented informed consent process on the IEC, DUPMCH approved informed consent forms.

While approving the Patient Information Sheet and the Informed consent Forms, IEC, DUPMCH ensures that the language used is to the level of understanding of the participant, contains all the essential information related to the study, translated documents in are available in Hindi and Marathi language, translation and back translation certificates are available, etc.

Informed consent process should be carried in such a way that the study participant understands each and every aspect and are answered for any & every query they have related to the study. It shall be taken care to use the language that the participants understand. Research participants should be given time as much as is needed by them to reach to the decision of their participation. It shall be taken care to avoid therapeutic misconception where the participants over-estimates the benefits or under-estimates the risk associated with the study which in turn affects their ability to provide voluntary and knowing informed consent.

In case where the subject is not able to provide informed consent (e.g Unconscious person or a minor etc,) all the information related to study shall be provided to the legally acceptable representative. If the subject or his/her LAR is unable to read/write – an Impartial Witness (IW) shall be present during the entire informed consent process.

The required essential documents of informed consent should be discussed with participants using approved ICF. Investigator shall constantly check the level of understanding of the subject asking the open-ended questions which results in obtaining legally effective informed consent document from subject. The copy of the signed ICF shall be given to the patient and the original shall be retained by the Principal Investigator.

IEC, DUPMCH may conduct surprise visit to the Informed consent site when the consenting process is going on by the Investigator. IEC, DUPMCH can also interview the participants to confirm the appropriateness of the Informed consent taken by the investigator.

Informed consent form is revised after assessing the need based on changes to the protocol, events occurring within the study, which increase risk to the study subjects, or as directed by the sponsor. ICF with concerned changes requested by the sponsor and/or investigator, when directed by the IEC, DUPMCH, re-consent the previously enrolled subjects with the revised, EC approved version of the informed consent form.

In case of clinical trials on pediatrics, the subjects are legally unable to provide written informed consent, and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case,

(i) Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.

(ii) Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.

(iii) Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

Essential Elements of Informed Consent Form

A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the informed consent form for trial subject is as per New Clinical Trial Rule, 2019 (Refer Annexure11)

Audio-Video Recording

Audio-visual recording of Informed Consent Process shall only be mandatory for cases where vulnerable population is involved & the trial is of New Chemical Entity or New Molecular Entity. For clinical trials of Anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent Process shall be mandatory. Audio-visual recording can be required as and when required by Ethics Committee.

The Investigator must provide the subject/LAR/IW with the information described in the informed consent section before signing the informed consent by the subject.

The language of information should be non-technical and understandable by the study subjects/ LAR/ IW and the same shall be recorded through audio-visual means. Details of questions if any, asked by the subject/ LAR/ IW and his/her understanding on consent are also to be recorded through the audio video recording. The process of signing/ putting thumb impression by the subject/LAR/IW should also be video recorded.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible should be kept confidential. The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects.

The trial data of subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

To maintain the confidentiality, the videographer should also be recruited as part of the study team. Prior to initiation of the study, the Investigator should define and allocate the activities of audio- Video recording of informed consent process to the respective identified person as videographer and should be mentioned in the study log of roles and responsibility of research staff.

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial. Audio-visual recording of informed consent process and other related documents should be preserved safely 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.

Proposal involving vulnerable population and special group

(Refer Annexure 8)

Advertisement

EC reviews advertisement to ensure that advertisement do not exaggerate the outcome and benefits than actually mentioned in consent document or protocol, do not emphasize on payment or free treatment, or Include exculpatory language. Example: In the event that you suffer a research- related injury, your medical expenses will be covered by your medical insurance.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as: The name and address of the researcher or research facility, The purpose of the research or the condition under study, In summary form, the criteria that will be used to determine eligibility for the study.

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

IEC, DUPMCH shall review the Clinical Trial Agreement/Memorandum of Understanding and Indemnity Agreement documents. IEC, DUPMCH shall ensure that the indemnity and compensation are appropriate and as per the applicable standards. It shall be taken care that the drug trial is started only after the agreement is signed by all the concerned parties (PI, Sponsor and HOI).

14. CONDUCT OF MEETING

IEC, DUPMCH meeting shall be conducted at scheduled interval preferably once every three months. However, depending upon the load of the Research Proposal, Meeting can be called upon as and when required. The final IEC, DUPMCH meeting date shall be informed to all the members well in advance to ensure their availability for meeting.

The Secretariat shall be the convener with overall responsibility for organizing the IEC, DUPMCH meeting from preparing agenda to communicating the decision of the IEC to the Investigator.

For the meeting, the following deliberations shall be made, if full quorum is available.

- Declaration of conflict of interest
- Confirmation of Last meeting’s minutes
- Action taken for the Last meeting
- Details of risk-benefit assessment decision of review of proposal

- Any changes requested
- Protocol Deviations, Adverse events/SAEs
- Non-Compliance
- Monitoring sites, reports, and Corrective and Preventive action (CAPA) plan; if any,
- Any other relevant discussions/updates

Before Meeting

- Member Secretary will prepare the Agenda of the IEC, DUPMCH meeting.
- The hard copy of the Research Proposals shall be circulated to all members prior to 3 weeks along with the agenda of the meeting and action taken on the previous meeting. Agenda of the meeting will also be sent to all the members via email, if required.
- Member Secretary prior to meeting ensures that there is no conflict of interest with any of the IEC members due to his/her participation in the protocol which are going to be reviewed; If it is found then Secretary will seek the concerned EC member to declare the same in conflict of Interest form (Refer Annexure 15) and then excuse themselves for that particular protocol review and decision making process. In case if quorum requirement is not fulfilling due to the COI of any EC member on the day of IEC, DUPMCH meeting then the meeting will be Re-scheduled or cancelled.
- All the Investigators shall be informed via letter to be present for the meeting to present his/her protocol to the IEC, DUPMCH members.
- All IEC, DUPMCH meetings will be held at the DEAN OFFICE DUPMCH, unless otherwise specified. Good working conditions in the room along with IT and Technical support will be ensured.

Conduct of Meeting

- Members should gather for the meeting on schedule date and time.
- At the beginning of each convened IEC, DUPMCH meeting, the member secretary will discuss and announce to declare if there is any conflict of interest with any of the IEC,

- DUPMCH member and informs that member having a conflict of interest must excuse themselves from deliberations and decision on that research proposal.
- If the unanticipated conflict of interest affects quorum, that particular item will not be discussed and will be deferred to the next scheduled meeting.
- Research involving vulnerable populations will be placed on to the agenda only when at least one individual (IEC member or Independent consultant/subject expert) who is knowledgeable and experienced in working with the population will participate in the meeting.
- Secretariat shall obtain signatures on confidentiality, Conflict of interest, if any, attendance, etc.
- Chairperson will initiate the meeting and secretary shall discuss the minutes of the previous meeting, action taken for the major/pending issues discussed in previous meeting and agenda for the current meeting.
- Principle Investigator shall be invited to present their proposals, and clarify doubts, if any.
- In case the secretary of the IEC, DUPMCH is the Principal Investigator for the project under review, the IEC, DUPMCH member nominated as acting Member Secretary will perform the function of the Secretary only for that study. The secretary should declare his/her conflict of interest and leave the meeting room.
- In Case the lead discussant cannot attend the meeting, the Co-Investigator or Secretary, IEC, DUPMCH or any other member of IEC may brief the IEC, DUPMCH about the research study.
- IEC, DUPMCH will completely review the research studies submitted. The committee will review new studies, amendments, annual/continuing review of ongoing studies, SAE reports, any other documents, and assess final reports of all research activities through a scheduled agenda.
    - The member Secretary, IEC, DUPMCH/ IEC, DUPMCH administrator minutes/records the proceedings of the IEC, DUPMCH meeting.
    - The decision shall only be made at the meetings where a quorum is present

- Only IEC, DUPMCH members who attend meeting will participate in the decision.
- It is the right of IEC member to disagree to approval of proposal. He/she has to give written explanation for disagreement.
- In each decision, voting of members shall be done. Voting Reference sheet (Refer Annexure7) will be kept as an evident of voting of each member. Based on voting the decision shall be taken.

After the Meeting

- The Member Secretary and IEC administrator will compile the meeting proceedings in a concise and easy to read style.
- The minutes will record whether the decision was unanimous, or whether the vote was taken for the decision. The number of members voting for, against and abstaining will be recorded.
- Conflict of interest; if any will also be included in the meeting minutes.
- The basis for requiring changes in or disapproving research; and a written summary of controversial issues and their resolution must be recorded.
- The draft minutes will be finalized by member secretary and will be circulated amongst the other members and Chairperson within a week of the meeting via an email.
- Any comments/changes requested by any member will be discussed /included by the member secretary. The final minutes of meeting will be signed by Member Secretary and Chairperson.
- Original version of the minutes will be placed in the minutes of meeting file
- A copy of decision letter along with all project related correspondence shall be placed in the appropriate project files.
- The Member Secretary shall convey the decision in writing to the Principal Investigator of the study preferably within10 days of the meeting.

15. DECISIONS MAKING AND POST MEETING ACTIVITIES

The IEC, DUPMCH shall provide complete and adequate review and based on that approval of the research Proposals submitted to them. The following points will be considered while doing so:

- An IEC member will withdraw from the meeting for the decision procedure concerning the study where the conflict of interest exists.
- If any IEC member has his/her own proposal for IEC review he/she will not participate in the IEC discussion or vote on that particular project.
- The documents required for full review of the application should be complete and the relevant elements considered before a decision is made.
- Only IEC members who attend the meeting will participate in the decision.
- The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
- The decision must be taken by majority opinion amongst the voting members of IEC after the quorum requirements are fulfilled to recommend/reject/suggest modification for a repeat review or advice appropriate steps.
- Subject expert/s may be invited to offer their views, but expert/s should not participate in the decision making process. However, his/her opinion must be recorded.
- Voting Procedure:
    - By signing the voting reference with marking Approved /Not approved/Conditional Approval suggested.
    - All the members except the Chairperson are entitled to one vote. However, in case of a tie, Chairperson will vote to break the tie.
- The secretariat shall communicate the decision in writing to the investigator within 10 days. The concurrence/Voting of the member will be recorded in the minutes as–
- Agreed: in favour
- Disagreed: Against
- CA: Conditional Approval

- After the meeting the committee may make one of the following recommendations.
- `Approved:` The study is approved in its present form
- `Approved subject to modifications:` This is a conditional approval indicating that the proposal is approved in principle, subject to the submission of certain clarifications, minor revisions, or additional documents. These will be reviewed by the member secretary, IEC on behalf of the full board. IEC, DUPMCH will empower member secretary to review the revisions/changes and grant approval if the revision/changes, clarification or additional documents are found satisfactory. The duration of time of responding back for the principal investigator shall not exceed more than 1 month.
- `Resubmit:` Extensive revisions are necessary. Principal investigator has to comply with the changes suggested by IEC and respond to the queries. The revised project will then be reviewed in the next full board meeting.
- `Deferment:` Indicating that proposal is not approved as submitted but it can be re-assessed after revisions, justifications, or additional information to address the specific reason(s) for deferment. Decision can't be arrived at present and therefore postpone to next meeting.
- `Not approved:` Indicates the study is not approved in its current form because members concerns for the protection of the participants have not been satisfactorily addressed even after the revision. A negative decision shall be supported by clearly stated reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC secretariat.
- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ratio/safety of the participants.
- In case of premature termination of study, notification shall be made indicating the reason for termination along with the summary of result conducted till date.
- The following circumstances require the matter to be brought to the attention of IEC.
- Any amendment to the protocol from the originally approved protocol with proper justification;

- Serious and unexpected adverse events and remedial steps taken to tackle them;
- Any new information that may influence the conduct of the study.
- The proceedings of the IEC meeting will be documented and the meeting minutes will be signed by the member secretary.

16. MONITORING

Site Monitoring Visit

It is the responsibility of the IEC, DUPMCH to monitor approved studies at the site. IEC, DUPMCH will perform on-site inspection of all approved ongoing studies at least once a year. Apart from the routine visits, additional visits could also be planned for the following:

- frequent protocol deviations,
- principal investigator carrying out large number of the studies at a time,
- in case of serious adverse event reported,
- non-compliance to approved protocols,
- Complaint received from Participants or any other cause as decided by IEC, DUPMCH

The selection of study for the monitoring will be discussed in the schedule IEC, DUPMCH meeting. The Chairperson will identify and designate one or more IEC members in site monitoring subcommittee or appoint an in dependent monitor to carryout monitoring of the study at site.

The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visits.

- The IEC members/Independent monitor along with IEC members will-
    - Check the log of delegation of responsibilities of study team
    - Check if the site is using latest IEC, DUPMCH approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
    - Review the informed consent document to make sure that the site is using the most recent version,
    - Observe the informed consent process or audio visual consent or audio consent, if possible.
    - Review randomly selected participants files to ensure that participants are signing the correct informed consent,
    - Observe laboratory and other facilities necessary for the study at the site, if possible. Review the project files of the study to ensure that documentation is filed appropriately.
    - Review the source documents for their completeness.
      Collect views of the study participants, if possible.
      Review the Site Master file an Investigational Products' storage and temperature
      Fill the Study (site) Monitoring Visit Report Form (Refer Annexure12)
- After the visit, member secretary will prepare a compiled report from individual monitors' site monitoring visit forms and their comments. This report shall describe the findings/observations of the monitoring visit.
- Member secretary will present the monitoring report at the next full board IEC, DUPMCH meeting and the concerned IEC member/independent monitor will provide additional details/ clarifications to members, as required.
- The IEC, DUPMCH shall discuss the findings of the monitoring process and decide appropriate specific action to be taken. Some of the actions which can be taken are as follows:
    - Continuation of the project with or without changes,
    - Restrictions on enrolment,
    - Recommendations for additional training,

- Recruiting additional members in the study team,
- Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
- Suspension of the study, etc.

- The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form
- The final decision taken at the full board IEC/the site monitoring visit report by the Chairperson is recorded in the Site Monitoring Visit Report Form
- The Secretariat will retain the copy of the report in the protocol file.
- The copy of IEC, DUPMCH subcommittee report on Site Monitoring Visit will be shared with a forwarding letter to the P.I.

Continuing Review of Study Protocols

- IEC, DUPMCH shall ensure to receive and review progress report every six month and minimum yearly after the initiation of the study for both the clinical trials, academic trials and biomedical and health research studies. All Academic research, review progress report shall be as per Annexure14.
- For clinical trials, progress reports will be discussed in a full board meeting. Based on the review and discussion in a IEC, DUPMCH meeting, the decisions will be recorded and communicated to PI in writing by the IEC, DUPMCH as 1) noted, when IEC, DUPMCH approves the project to be continued without any modifications, 2) Modification recommended, when the modifications suggested by IEC, DUPMCH needs to be amended by PI and then resubmission has to be done by the PI, 3) or the discontinuation of the project. Further, if there are any significant findings that have been observed during review process, this will be communicated to Principal Investigator.
- The final decision taken about the study will be communicated to PI within 10 days of the meeting.
- Investigator shall provide the response within 21 days to the IEC, DUPMCH.

- IEC, DUPMCH should review the SAE reports from the site as well as from other sites and should take appropriate action.

Adverse Events and Serious Adverse Event Monitoring:

All serious, unexpected and associated events shall be notified by PI to the Ethics committee as per regulatory requirement. The primary responsibility of IEC, DUPMCH is to review and address SAE and unexpected events involving risks to the research participants as per New Drugs and Clinical Trial Rules 2019.

Reporting Timeline of the SAE:

- All SAEs including Deaths should be reported by the Principal Investigator within 24 hours of their occurrence to IEC, DUPMCH, Sponsor or its representative, CDSCO (in case of studies that require approval of the CDSCO) and head of the Institute as per the format specified in New drugs and Clinical Trial rules, 2019
- Secretariat will be responsible for receiving all the documents pertaining to the adverse event.
- In case of SAE, the report with due analysis will be submitted by the Principal Investigator within 14 calendar days.
- In case of SAE, the report with due analysis will be submitted by the sponsor within 14 calendar days.
- Investigator is responsible for sending all follow up reports for all onsite SAEs till the event is resolved.
- In case the event is Death due to disease progression, the event should be notified in the SAE reporting format unless specified in the protocol.

- Upon receipt of any SAE related report, the IEC, DUPMCH secretariat will verify that the report is complete and is duly signed and dated by the Principal Investigator or the Sponsor as the case may be. If the report has been received beyond the specified time, this will be considered as a violation.
- Member secretary will sign and write the date and type of report on which the report is received and then will forward the same to subcommittee for SAE.
- For Initial SAE Reported within 24 hrs of the occurrence, an expedited review will be conducted by IEC, DUPMCH members at least within 3 working days of the receipt of the SAE report. The subcommittee may be formed to investigate the case in detail at site.
- If it seems necessary during expedited meeting, the committee can recommend immediate actions to be taken for the study at site.
- The IEC, DUPMCH secretariat will draft a formal letter to the concerned Principal Investigator and will inform him/her about the IEC, DUPMCH decision taken during the meeting or queries raised by the subcommittee during investigation within 7 days.
- After receiving due analysis report from PI within 14 calendar days and query response from PI regarding the raised queries, a full board IEC, DUPMCH meeting shall be conducted within a week.
- The SAE will be discussed at the full board meeting. The subcommittee if formed shall present their opinion on the causality assessment. The Chairperson will invite all members to voice their opinions and ensure free discussion.

The consensus decision shall be made during the meeting which requires the specific actions. Some of them are as follows:

- Direct the PI to re-evaluate the event as to whether it is AE/SAE and report to IEC.
- Request further follow up information or additional details
  Recommend an amendment to the protocol, ICD, or any other study related document

- Suspend the study for a fixed duration of time/additional information is obtained/review is completed.
  Suspend enrolment of new research participants;
- Terminate the study.
- Any other appropriate actions.

Any of the above recommendations shall be communicated to the Investigator in writing or through telephone or email, within 24 hours.

IEC, DUPMCH shall determine the causality (Relationship of the SAE with the study drug) with the expertise, experience and skill reviewer if required.
In case of serious adverse event or death occurring to the clinical trial subject, &/or Biomedical and Health Research the IEC, DUPMCH shall forward its due analysis decision for quantum of compensation determined as per the formula specified in the, New drugs and Clinical Trial rules, 2019 to be paid by the sponsor or its representative and shall pass orders as deemed necessary within ninety days of the receipt of the report of the serious adverse event.

IEC, DUPMCH shall calculate the compensation to be paid to the subject based on New Drugs and Clinical Trial Rules 2019. (Refer Annexure 13)

All off site SAEs shall be notified by PI to IEC, DUPMCH. Offsite SAEs if required may be discussed in IEC, DUPMCH meeting and will be filed in respective project file.

- Onsite AE:

  All the onsite adverse events shall be recorded by PI and shall be notified to IEC, DUPMCH.

  Member secretary shall be responsible for reviewing adverse event notification. If required Member secretary may inform Investigator to present the adverse event reported to the members of the IEC, DUPMCH in a scheduled full board meeting.

The reported adverse event shall be discussed in a meeting and the deliberations shall be recorded in detail in minutes of that meeting.

Appropriate actions shall be taken by IEC, DUPMCH depending on the severity and nature of the adverse event and relatedness of the event with the study drug.

IEC, DUPMCH may also send the letter to PI for justification or clarification or further information on any AE reported.

Protocol Deviations/Violations:

IEC, DUPMCH is responsible for receiving non-compliance reports and taking appropriate actions after thorough review and discussion.

Protocol violation: A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Examples of protocol violations may include the following:

- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events
- Improper breaking of the blind
- Use of prohibited medication
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel
- Incorrect or missing tests
- Mishandled samples

`Protocol Deviations:` Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data.

- Deviations may result from the action of the subject, researcher, or research staff. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non- compliance with the research protocol on the part of a researcher.

Examples of a deviation include:

- A re-scheduled study visit
- Failure to collect an ancillary self-reported questionnaire
- Subject's refusal to complete scheduled research activities

The Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC, DUPMCH. The IEC, DUPMCH members performing monitoring of the project at trial site may also report any protocol deviation/violation/noncompliance observed. The Secretariat can detect a protocol deviation/non- compliance/violation from failure to comply with statutory requirement/failure to respond to requests from IEC, DUPMCH within reasonable time limit. The members of the IEC, DUPMCH may also detect protocol deviation/violation while scrutinizing study progress report. The Protocol deviation/violation reports may also be received from research participant or independent person or from Head of the Institution.

- Each allegation is taken seriously and reviewed in a consistent, prompt, and professional manner. Additionally, care is taken to maintain confidentiality.
- The Chairperson/IEC members will review the information available and take a decision depending on the seriousness of the violation.

- The decision will be taken to ensure that the safety and rights of the research participants are safe guarded.
- The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.

The actions taken by the IEC could include one or more of the following:

1. Determine that no further action is required, or take other actions as appropriate.
2. Suggest modifications to the protocol
3. Require additional training of the investigator and study team.
4. Reprimand the PI.
5. Observe the research or consent process.
6. Enlist measures that the PI would undertake to ensure that such deviations/noncompliance / Violations do not occur in future.
7. Suspension or termination of the study, etc.

- The decision will be communicated to the PI within 14 days except if the decision is project suspension/termination, which will be communicated to the Principal Investigator within 1 working day of the meeting.
- The Secretariat will record the decision reached on the protocol deviation / violation in the minutes of the meeting.

17. SUB-COMMITTEE(S) OF IEC, DUPMCH

* For Review of SAE / AE/ SOP preparation/any other activity, subcommittee would be formed by the chairman as per requirement: A sub-committee would examine all amendments, adverse events and serious adverse events reported / submitted to the IEC, DUPMCH and present them to the full IEC, DUPMCH for comments and approvals. The investigators would not be required to be present while these are discussed at the IEC meeting.

Compensation: New sub-committees may be constituted as and when required for such purpose. A sub-committee would examine seriousness criteria and performs causality assessment for Serious Adverse Events and based on that calculates subject compensation as per New drugs and CT rules 2019. Protocol Amendment/Revision: A sub-committee would be formed as and when there is a requirement of amendment/Revision of the EC SOP.

18. PRINCIPAL INVESTIGATOR'S RESPONSIBILITY

Principle investigator shall be overall responsible for keeping the IEC informed about every aspect of the ongoing study.

- A Principal Investigator shall not be concurrently running more than three clinical trials.
- PI shall notify IEC, DUPMCH about the Site initiation visit and First Patient Randomization.
- All SAEs and the interventions undertaken would be intimated and recorded as document filled in the ADR form along with causality assessment.
- Protocol deviation, if any, would be informed with adequate justifications.
- Any amendment to the protocol would be resubmitted for renewed approval.
- Any new information related to the study would be communicated.
- Premature termination of study would be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites would be informed.
- Inform IEC about study completion or discontinuation with reasons.
- Justification for approval to restart studies discontinued earlier.
- The PI must register the Clinical trial with CTRI within 2 weeks of IEC approval letter and inform the IEC of the CTRI registration number before starting trial.
- Progress reports (Refer Annexure 14) are to be submitted six monthly in case of Academic trials.

- In case of clinical trials, PI shall sent the study progress report to IEC, DUPMCH which must include overall recruitment status of the site, any AE or SAE reported, any revisions/amendments in approved protocols, protocol deviations/violations if any reported, etc.
- Final clinical study report should be submitted by PI at the end of study.

FOLLOW UP PROCEDURES:

In case of all Biomedical and Health Research, six month progress report shall be submitted by the PI to IEC, DUPMCH in prescribed format as given in Annexure 14.

- In case of clinical trials, PI shall sent the study progress report to IEC, DUPMCH which must include overall recruitment status of the site, any AE or SAE reported, any revisions/amendments in approved protocols, protocol deviations/violations if any reported, etc. This shall be reviewed in the forthcoming full board IEC, DUPMCH meeting. If deemed necessary by the member secretary, the Investigator may be informed to present the study progress report in a scheduled IEC, DUPMCH meeting.
- The detailed discussion of this progress report amongst the IEC, DUPMCH members shall be captured in the minutes of the meeting.
- All clinical trial approvals are of one year duration. If recruitment of the trial is of longer than one year, or if follow up of the patient is for longer duration, PI will have to take annual renewal from IEC, DUPMCH. The PI has to submit annual report and fees as per IEC, DUPMCH norms. PI will represent the report in forthcoming IEC, DUPMCH meeting and to get renewal for the study one more year.
- For all Biomedical and Health Research upon completion, PI will request IEC, DUPMCH to issue the approval letter. IEC, DUPMCH upon checking the abstract, progress report, plagiarism report (in case of Dissertation study), and master chart of data gathered, will issue a completion certificate to PI.
- For all clinical trials, PI will notify to the IEC, DUPMCH about the study completion status of the site and the final Clinical Study Report (CSR).

19. RECORD KEEPING AND ARCHIVING

- CV of all members of IEC, and Confidentiality agreement, minutes of all meetings duly signed by the Chairperson/ and Member Secretary, Copy of all correspondence with members, researchers and other regulatory bodies and all study related documents (study protocols with enclosed documents, progress reports, and SAEs) shall be archived for minimum of 5 years after the completion of study.
- If facilities are available, the IEC, DUPMCH will make a soft copy of the documents and store in the archive office of IEC, DUPMCH. All documents related to the study file will be gathered, classified and combined together appropriately.
- All active files will be kept in a secured file cabinet with controlled access. Only authorized individuals i.e. Secretary/Chairperson, or person authorized by them will have access to the files.
- All closed study files shall be separately archived.
- The completed/closed project files will be stored in archive boxes that are clearly labelled with the project number and title, name of PI and disposal date. The archive boxes will be sent to a secure, dry location. The access to the files should be restricted to the IEC and the regulatory authorities. The details of the archiving location should be recorded in a location register stored in the IEC office. This register should record the project number and title, name of PI and the disposal date.

Retrieving Documents

The request for retrieval shall only be made by an IEC, DUPMCH member, auditor or other authorized person by writing an application stating the purpose and signing & dating the application letter.

A member of IEC Secretariat will retrieve archived document(s) and will return the remaining file back to its place.

The Secretariat maintains a register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC Chairperson, Date and time of retrieval, Name and signature of IEC staff / Secretariat retrieving the file, Date and time of returning the file

The Secretariat will also record, sign and date when the document has been returned and kept.

Disposal of Files

The study file will be maintained in the IEC office for a period of five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off. However, all the copies of the research projects and documents submitted for IEC review shall be shredded by the authorized IEC personnel after the IEC meeting without any notification to the PI. A logbook of disposed documents will be maintained.

ANNEXURES

ANNEXURE 1: RESEARCH PROPSAL SUMMARY SHEET

(To be filled by Principal Investigator)

Title of the Project	**:**	_____
Name of Principal Investigator	**:**	_____
Designation	**:**	_____
Department	**:**	_____
Institute	**:**	_____
Email ID	**:**	_____
Contact No.	**:**	_____
Name of Co-Investigator(s)/Guide)	**:**	_____
Designation	**:**	_____
Department	**:**	_____
Institute	**:**	_____
Email ID	**:**	_____
Contact No.	**:**	_____
Proposed Budget in Rs.	**:**	_____
Project Submission Date	**:**	_____
Funded By	**:**	Self ☐ External ☐ DUPMCH ☐
Type of Study Design	**:**	☐ Observational ☐ Cross Sectional ☐ Interventional ☐ Case Control ☐ Laboratory ☐ Cohort ☐ Animal ☐ Comparative ☐ Retrospective ☐ Randomized ☐ Comparative

Duration of the Projects (in Months) :_____

Any Change after IEC DUPMCH Approval : _____

Specify Changes : _____

Submission Date : _____

HRRP Remarks : _____

Checklist for Research Proposal Submission

SR.NO	CONTENTS	YES/NO/NA
1	Covering letter of submission signed by investigators and forwarded by HOD/off. In charge	
2	Title or cover page	
3	Introduction	
4	Aim and objectives	
5	Review of literature	
6	Materials and methods	
	A. Study design	
	I. Place of study	
	II. Source of data	
	III. Related approvals	
	IV. Sample description	
	V. Selection criteria	
	1. Inclusion criteria	
	2. Inclusion criteria	
	B. Material/equipment for the study	
	C. Methodology	
	D. Informed consent form (in arati &English)	
	E. Participant information sheet (In arati & English)	
7	Statistical method	
8	Ethical issue	
9	Feasibility issue	
10	Likely outcome/benefit of study	
11	Conflict of interest	
12	Sponsors of the study, if any	
13	Sources of fund, if any	
14	Expenditure statement	
15	References (Superscript and Vancouver style)	
16	Signature of principal investigator/PG Guide	

Principal Investigator **Guide**

ANNEXURE 2: FORMULATION OF NEW SOP/REVISION OF SOP

SOP No.		
Title		
Need/Reason to Formulate New/Revision of the SOP		
Identified by :		Date:
Discussed in IEC meeting held on :		
SOP Revision Required	Yes ☐	No ☐
New SOP to be formulated	Yes ☐	No ☐
If yes, to be carried out by whom?		
If no, Why?		
Date of SOP revised		
Date SOP approved		
SOP effective date:		

ANNEXURE 3: DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITALINSTITUTIONAL ETHICS COMMITTEE
MEMBERSHIP LIST w.e.f.29th Sept, 2021.

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail I . D . and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Parag Ramchandra Patil	PHD Neuropharmacology	KYDSCT's college of Pharmacy	9890864219 drparagpatil@gmail.com KYDSCT'S college of Pharmacy, Sakegaon , Taluka Bhusawal, District, Jalgaon, 425201	Chairman	No
2	Dr. Rahul Prakash Bhavasar	MD Pharmacology	Dr. Ulhas Patil Medical College And Hospital	9619419807 rahulprakashbhavasar@gmail.com Department of Pharmacology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Member Secretary	Yes
3	Dr. Vaishali Baburao Nagose	MD Pathology	Dr. Ulhas Patil Medical College And Hospital	8500571871 vaishali.nagose@gmail.com Department of Pathology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Basic Medical Scientist	Yes
4	Dr. Shubhangi Devendra Chaudhari	DNB OBGY	Dr. Ulhas Patil Medical College And Hospital	9765972347 shubhangi121277@gmail.com Department of Obstetrics & Gynaecology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Clinician	Yes
5	Adv. Satish Govindrao Gadge	LLM	Private Practice	7387193453 satishgadge60@gmail.com C/O P-51, MIDC, Girl's hostel quarters, Godavari college of engineering, Jalgaon Bhusawal road, 425003	Legal Expert	No
6	Dr. Prashant Sudhakar Warke.	MBA	Godavari Institute of Management and Research	9325150006 warke.prashant01@gmail.com Godavari Institute of Management and Research, Plot no P-54, near Bhart Petroleum, Addl MIDC, Bhusawal road Jalgaon 425003	Social Scientist	No
7	Mrs. Swara Jayesh Waghodkar	B. Com	House wife	7350043418 jwaghodkar@gmail.com Nagosen colony Kandhari, Bhusawal, Jalgaon 425201	Lay Person	No

8	Dr. Nilesh Prakash Bendale	MD Community Medicine	Dr. Ulhas Patil Medical College And Hospital	9604692540 nileshbendale@rediffmail.com Department of Community Medicine, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Basic Medical Scientist	Yes
9	Dr. Shivaji Pandurangrao Sadulwad	MS General Surgery	Dr. Ulhas Patil Medical College And Hospital	9881604567 dr.shivajisadulwad72@gmail.com Department of Surgery, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Clinician	Yes
10	Mr. Girish Ashok Kulkarni.	PHD Electrical Engineering	HSM's Shri Sant Gadge Baba College of Engineering and Techniology, Bhusawal,	9767393498 girish227252@gmail.com Shikshak colony, shanti nagar, behind dnyneshwar garden, near hanuman mandir, Bhusawal, 425201, Jalgaon, Maharashtra.	Philosopher	No

ANNEXURE 4: CONFIDENTIALITY AGREEMENT FORM FOR INDEPENDENT CONSULTANTS

I,_____ (Name and Designation) as a non-member of IEC understands that the copy/copies given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

_____ _____

Undersigned Signature Date

_____ _____

Chairperson of IEC Date

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

_____ _____

Signature of the recipient Date

ANNEXURE 5: ONE PAGE CV FORMAT FOR IEC, DUPMCH MEMBERS/INVESTIGATORS

Curriculum Vitae

Full Name	**:**	
Date of Birth	**:**	
Designation	**:**	
Language Proficiency	**:**	
Professional Mailing Address	**:**	
Contact No.	**:**	+91
Email ID	**:**	

Academic Qualifications		
Degree/Certification	**Date (YYYY)**	**Institution, Country**
Medical Registration Number		

Current and Previous Relevant Positions Including Academic Appointments		
Start and End Date	**Title**	**Institution or Company, State/Province/Country**

ICH – GCP Training **:** Yes / No, if Yes then specify month & year
NDCT RULES 2019
Research Experience

Signature: **Date:**

ANNEXURE 6: CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT FORM

In recognition of the fact, that I,…… here in referred to as the "Undersigned", have been appointed as a member of the Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital and would be asked to assess research studies involving human participants in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines; Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

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

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

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

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

Undersigned Signature Date

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

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

The Undersigned will immediately disclose to the Chairperson of the IEC all conflicts of interest for themselves and their spouses/domestic partners and dependent children.

Agreement on Confidentiality and Conflict of Interest

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

Whenever I have a conflict of interest, I shall immediately inform the committee and recuse myself from discussion and /or voting on the issue and leave the room while the discussion is ongoing"

Whenever I have a conflict of interest, I shall immediately inform the committee all conflicts of interest for myself and my spouses/domestic partners and dependent children.

Name of the spouses/domestic partners (if applicable) :_____

Name of the dependent children (if applicable) :_____

I, Dr. ……. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

_____

Undersigned Signature Date

_____

Chairperson, DUPMCH

Date:-

ANNEXURE 7: VOTING REFERENCE

Protocol Title:
Protocol Number:
Principal Investigator:
Reviewed in EC meeting dated:

Sr. No	Member Name	Role in EC	Approved	Sign & Date
1			Y/N/CA*	
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

(*CA – Conditional Approval)

The committee empowers the member secretary to grant permission, if PI compiles to the raised query within 30 days.

ANNEXURE 8: STANDARD OPERATIVE PROCEDURE (SOP) FOR SPECIAL/VULNERABLE POPULATIONS

Studies in special populations:

Vulnerable populations are those that are relatively(or absolutely)incapable of protecting their own interest, either due to insufficient power, intelligence, education, resources, strength, or other needed attributes. Hence, they lack the capacity to provide informed consent or their willingness to participate in research and may be unduly influenced.
The special/vulnerable populations include pregnant women, fetuses and neonates, children, prisoners, students, employees of the sponsor or investigator and economically or educationally disadvantaged persons.
The investigator is required to indicate the involvement of potentially vulnerable populations/group to the IEC, DUPMCH in the application documents (usually in the protocol) and provide description of the safeguards to protect the rights and welfare of the vulnerable participants.

1. Research involving pregnant women, fetuses and neonates.

The IEC, DUPMCH may approve the research involving these participant populations if they satisfy the following conditions.

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals and clinical studies, including the studies on non-pregnant women have been conducted for assessing potential risks to the pregnant women and fetuses.
- A risk to the fetus is caused solely by the inventions or procedures which are of the direct benefit for the woman or the fetus.
- Where the risk to the fetus is not greater than minimal and the purpose of the research is the development of the biomedical knowledge which cannot be obtained by any other means.
- When there is a least possible risk for achieving the objectives of the research.
- When the research holds out the prospect of the direct benefit to the pregnant woman

Research involving the neonates:

A. After delivery: The neonates may be involved in the research if all of the following conditions are met with.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted for
   assessing the potential risks to the neonates.
2. The individual(s) providing consent under the applicable regulations is/are fully informed about the reasonably foreseeable impact of research on the neonate.
3. The regulatory requirements should be met as applicable.

B. Neonates of uncertain viability: After delivery, until it is ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by federal regulations unless the following conditions are also met with:

1. That the research holds the prospect of enhancing the probability of survival of the neonate, and any risk if expected should be the least for achieving the objectives.
2. Purpose of the research is development of the knowledge which cannot be obtained by other means and there will be no risk to the neonates that result from the research.
3. The legally effective informed consent of either parent of the neonate or, if neither of the parent is able to give the consent because of the unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative has to be obtained in accord with.

C. Nonviable neonates: After delivery, a nonviable neonate may not be involved in research covered by federal regulations unless the following conditions are met with.

1. Vital functions of the neonate will not be artificially maintained.
2. Research will not terminate the heart beat or respiration of the neonate.
3. There will occur no risk to the neonate from the research.
4. The purpose of research in the development of knowledge cannot be obtained by other means.
5. A legally effective informed consent of both the parent of the neonate should be obtained in accord with. However, if one of the parents is unable to consent because of unavailability, incompetence or temporary incapacity, the informed consent of the other parent will suffice to meet the requirements.

Research involving after delivery: The placenta, the fetus, fetal material, tissue or organs excised from a dead fetus. Such research shall be conducted only in accordance with the applicable federal, state, or local laws regarding such activities

Research involving pregnant woman:

Research involving the pregnant woman is not allowed until and unless

- The research includes adequate provisions to monitor the risks to the participant and to the fetus
- The potential participant is selected with adequate considerations.
- Adequate provision is made to monitor actual consent
- The research is continually evaluated to determine if any unanticipated risk have arisen.

2. Research involving the prisoners:

Prisoner include any individual who is confined or detained in a penal institution or sentenced to serve time in a penal institution under criminal or civil statute, or detained in other facilities by virtue of statutes or commitment procedure which provide alternatives to criminal prosecution or incarceration in a penal institution, or detained pending arraignment, trial or sentencing. Regulations do not differentiate between detention, jail or prison.

However, IEC, DUPMCH requires that if the enrolment for research in such population has to be held then the following conditions are to be met with:

- The study causes, effects and processes of incarceration no more than minimal risk and no more inconvenience to the participants.
- The study should present no more than minimal risk and no more than inconvenience to the participants.
- The research under review involves solely research practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the participant.
- In cases where prisoners may not be benefitted from the research because they are assigned to a control group in consistence with the protocol approved then the study may proceed on federal approval.

- The risk involved in the research is commensurate with risks that would be accepted by non-prison volunteers.
- Unless the investigator provides justification in writing for following, some other procedures, control participants must be selected randomly from the group of eligible prisoners for the research project.

When an enrolled participant becomes a prisoner during a research:

- For the ongoing research projects, if an enrolled participant becomes a prisoner and the study not being reviewed and approved by the IEC, DUPMCH for the inclusion of prisoners , the investigator is responsible for notifying the IEC, DUPMCH as soon as possible and request determination from chair that in the best interest of the incarcerated prisoner participant to continue certain study interventions as a non-participant for patient safety reasons until such time he/she can be withdrawn from the study, otherwise the investigator will withdraw the now prisoner participant from the study as follows:
- If a participant becomes a prisoner after enrolment in research, the investigator must cease all the research interactions and interventions with the participant.
- The investigator shall report this situation to the IEC, DUPMCH in writing
- In special circumstances in which the principle investigator asserts that it is in best interests of the participant to remain in the research while incarcerated, the IEC, DUPMCH may determine the same and the participant may continue until the requirements are satisfied.
- At the earliest opportunity on receiving the investigator's notice or otherwise becoming aware of the incarceration of a participant, the IEC, DUPMCH shall review the protocol again with a prisoner representative as a member of IEC, DUPMCH. Based upon this review the involvement of the prisoner participant may be either approved or withdrawn.

3. **Research involving children:** Approval of the research in children is based on the probable risks, associated discomforts and possible benefits.

3.1 Determination of probable risks and associated discomforts:

The assessment of the probability and magnitude of the risk may be different for the sick children and may vary depending on the diseases or the conditions the participant may have. However, the IEC, DUPMCH shall consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk. The IEC, DUPMCH shall also consider the extent to which research procedures would burden any child, regardless of whether the child is accustomed to the proposed procedure. Depending on the degree of risk benefit to individual participants can be as follows

- Research not involving greater than minimal risk.
- Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants.
- Research involving greater than minimal risk with no prospect of direct benefits to individual participants, but likely to yield generalizable knowledge about the participants disorder or condition.
- Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate serious problem affecting the health or welfare of children.

3.2 Determination of possible benefits:

To assess the possible benefits of research in children, the IEC, DUPMCH shall consider the variability in the health statuses among the participants.

3.3 Wards of the state:

When the research involves greater than minimal risk to the participants with no prospect of direct benefit, the research must either be related to their status as wards, or be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards. Then, the IEC, DUPMCH shall require for each child who is a ward, appointment of an advocate in addition to any other individual acting on behalf of the child as a guardian.

3.4 HIV- infected children:

The IEC, DUPMCH shall give special attention to groups of children such as these, who need special protections, should not be denied the opportunity to participate in research that may potentially benefit them.

3.5 Institutionalized children:

The IEC, DUPMCH shall not allow the Institutionalized children to be included as participants simply because of their availability to the investigator.

3.6 Parental permission:

Children may be participants of research only if the Informed Consent from the parent or the legal guardian is obtained (**Refer Annexure 18)**. The IEC, DUPMCH shall determine whether the permission of both the parents is necessary, and the conditions under which one parent may be considered is not reasonably available.

3.7 Assent of children:

The IEC, DUPMCH shall determine whether adequate provisions are made for soliciting the assent of the children. The assent shall be obtained from the participating child in the format prescribed by IEC, DUPMCH.

3.8 Considerations for assent (as per guidelines of New Drugs and CT Rules 2019)

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

  (Refer Annexure 19).

4. Research involving Geriatrics:

Geriatric population is considered for research if the disease intended to be treated is characteristically a disease of aging; or the population to be treated is known to include substantial numbers of geriatric patients; or when there is specific reason to expect that conditions common in the elderly are likely to be encountered; or When the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient.

5. Other groups and research situations requiring special consideration:

Every project reviewed by the IEC, DUPMCH is evaluated for circumstances that may place participants in vulnerable situations and call for special protection. When a participant group is identified as being vulnerable in a particular research setting, the IEC, DUPMCH will consider whether the protocol provides adequate pretentions for those participants. The IEC, DUPMCH may require additional protections for safeguarding those participants as condition of approval. Some of such situations are described below.

Other special populations may include cognitively impaired participants, traumatized and comatose patients, terminally ill patients, students, normal volunteers, minorities, and participants in AIDS research, employees of the sponsor or investigator, and the elderly. The IEC, DUPMCH shall determine special protections necessary for these groups on a case by case basis, taking into account the risks and benefits.

5.1 Cognitively impaired participants:

The cognitively impaired participants are defined as having a psychiatric disorder (e.g. psychosis, neurosis, and personality or behavior disorders), an organic impairment (e.g. dementia) or a developmental disorder (e.g. mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is diminished.

5.1.1 Others include persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may be compromised in their ability to make decisions in their best interest. The IEC, DUPMCH shall determine the degree of risk of a research protocol involving cognitively impaired participants, a minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.

5.1.2 However, for the research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the participant's condition.

5.1.3 Studies involving the participants who are cognitively impaired may take place over extended periods. The IEC, DUPMCH shall consider whether periodic re-consenting of individuals is required to determine that a participant's continued involvement is voluntary. The IEC, DUPMCH may require that the investigators re-consent participants after taking into account the study's anticipated length and the condition of the individuals to be included.

5.2 Informed consent: Cognitive impairment alone should not disqualify a person from consenting to participate in research and making an informed voluntary choice; rather the investigator shall present specific evidence of cognitive impairment.

6. Research in schools:

When research will be conducted in schools, the IEC, DUPMCH will consider, whether protection required by the law that apply to research in schools, is adequately met with.

7. Students, employees and others in subordinate positions:

Students, employees and other persons in subordinate positions or positions of lesser power or status provides a pool of easily accessible research participants. The IEC, DUPMCH will consider whether the autonomy and confidentiality of these individuals are adequately protected, which may include the following;

- That incentives for participation do not present undue influence
- That participants have the ability to decline participation
- That confidentiality is maintained for self-disclosures of a personal nature
- For students, if course credit is given for participation, that alternatives are no more burdensome than the participation in research are available for receiving equal credit.

8. Economically or educationally disadvantaged persons and other groups requiring special consideration:

The economically or educationally or educationally disadvantaged, homeless persons, the elderly and the members of particular minor group are only some of the additional populations that may require special protection in the research environment. When such groups are specifically targeted as research participants, the IEC, DUPMCH will consider whether adequate safeguards are in place to protect such participant groups from risks unique to the population and that researchers do not use their position to unduly influence participation.

ANNEXURE 9: IEC, DUPMCH REVIEW CHECKLIST

Name of IEC member/Independent Consultant**:**
Protocol Reviewed:

Principal Investigator**:**

Sr. No	Topics of Review	Adequate/Relevant (Mark √ or ×)	Inadequate? Irrelevant (Please specify inadequacy
1	Covering letter bearing		
	a. Title of the study		
	b. Name and Sign of PI		
	c. Name of the guide		
	d. UG/PG/Clinical Research		
	e. Type of study, PhD, Research Project (Student/Faculty)		
2	Introduction		
3	Aim (s) & Objective (s)/ Rationale of the study		
4	Information Brochure/Review of Literature		
5	Protocol Design		
6	Statistical Methods		
7	Ethical Issues		
8	Feasibility Issue		
9	Likely Outcome/Benefit of the study		
10	References-		
	a. Cited Properly		
	b. Vancouver style		

Sr. No	Topics of Review	Adequate/Relevant (Mark √ or ×)	Inadequate? Irrelevant (Please specify inadequacy
11	Participant/Patient Information Sheet		
	a. English		
	b. Vernacular Language (arati		
	c. Vernacular Language (Hindi)		
12	a. Informed Consent Form English		
	b. Vernacular Language (arati)		
	c. Vernacular Language (Hindi)		
13	Case Report Form / Proforma/Questionnaire		
14	Financial Considerations and Clinical Trial Agreement (CTA),if Applicable		
15	Signature of Guide and Student		
16	Overall Comments		
17	Signature of IEC Member		

ANNEXURE 10: CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING

CLINICAL TRIALS

Title Page

(a) Full title of the clinical study,

(b) Protocol, Study number, and protocol version number with date.

(c) The Investigational New Drug (IND) name/number of the investigational drug.

(d) Complete name and address of the Sponsor and contract research organization if any.

(e) List of the investigators who are conducting the study, their respective institutional affiliations and site locations

(f) Name of clinical laboratories and other departments and/or facilities participating in the study.

Table of Contents

1. **Background and introduction:**

(a) Preclinical experience

(b) Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

2. **Study rationale:** This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.

3. **Study objective:** (primary as well as secondary) and their logical relation to the study design.

4. **Study design:**

a) Overview of the study design: Including a description of the type of study (i.e., double-blind, multicentre, placebo controlled, etc.), a detail of the specific

treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

b) Flow chart of the study

c) A brief description of the methods and procedures to be used during the study.

d) Discussion of study design: This discussion details the rationale for the design chosen for this study.

5. **Study population:** The number of subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the subject population required is also mentioned.

6. **Subject eligibility:**

   a. Inclusion criteria

   b. Exclusion criteria

7. **Study assessments**: plan, procedures and methods to be described in detail.

8. **Study conduct** stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing, electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.
   Each visit should be described separately as Visit 1, Visit 2, etc.

Discontinued subjects: Describes the circumstances for Subject withdrawal, dropouts, or other reasons for discontinuation of Subjects. State how drop outs would be managed and if they would be replaced describe the method of handling of protocol waivers, if any. The person who approves all such waivers should be identified and the criteria used for specific waivers should be provided.
Describes how protocol violations will be treated, including conditions where the study will be terminated for noncompliance with the protocol.

9. **Study treatment-**

a) Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency, and duration of concomitant treatment should be stated.
b) Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.
c) Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.
d) Possible drug interactions.
e) Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a Subject is not allowed to use during parts of or the entire study. If any washout periods for prohibited medications are needed prior to enrolment, these should be described here.
f) Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject.
g) Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given.

10. Adverse Events:

Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

11. Ethical considerations: Give the summary of:

a) Risk/benefit assessment:
b) Ethics committee review and communications
c) Informed consent process
d) Statement of subject confidentiality including ownership of data and coding procedures.

12. Study monitoring and supervision:

A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specific required in filling out the forms Case Record Form correction requirements, including who is authorized to make corrections on the Case Record Form and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

13. Investigational Product Management:

a) Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study).
b) The precise dosing required during the study.
c) Method of packaging, labeling, and blinding of study substances.
d) Method of assigning treatments to subjects and the subject identification code numbering System.
e) Storage conditions for study substances.
f) Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned or destroyed.
g) Describe policy and procedure for handling unused investigational products.

14. Data Analysis:

Provide details of the statistical approach to be followed including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (Primary as well as Secondary) and safety endpoints

Statistical analysis: Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned.

Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

15. Undertaking by the Investigator:

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

    i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
    ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
    iii. I agree to personally conduct or supervise the clinical trial at my site.
    iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
    v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
    vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
    vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and

they have been informed about their obligations in meeting their commitments in the trial.

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

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

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

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

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

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

8. Signature of Investigator with date.

16. Appendices:

Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.); Case Record Form (CRF) and other data collection forms; a summary of relevant pre- clinical safety information and any other documents referenced in the clinical protocol.

ANNEXURE 11: ELEMENTS OF THE INFORMED CONSENT

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

   i. Statement that the study involves research and explanation of the purpose of the research.
   ii. Expected duration of the participation of subject.
   iii. Description of the procedures to be followed, including all invasive procedures.
   iv. Description of any reasonably foreseeable risks or discomforts to the Subject.
   v. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
   vi. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
   vii. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
   viii. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
   ix. Statement describing the financial compensation and the medical management as under:
      (a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
      (b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.
   x. An explanation about who to contact for trial related queries, rights of Subjects and in the event of any injury.
   xi. The anticipated prorated payment, if any, to the subject for participating in the trial.

   xii. Responsibilities of subject on participation in the trial.

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

xiv. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

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

xvi. Any other pertinent information.

Additional elements, which may be required:

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

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

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

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

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

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

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

Informed Consent form to participate in a Clinical Trial Study Title:

Study title	:	
Study Number:	:	
Subject's Initials	:	
Date of Birth/Age	:	
Subject's Name	:	
Address of the Subject	:	
Qualification	:	
Occupation	:	Student or Self-Employed or Service or Housewife or Others (Please click as Appropriate)
Annual Income of the subject	:	

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

			Please initial box (Subject)
I.	I confirm that I have read and understood the information sheet dated……..for the above study and have had the opportunity to ask questions.	:	
II.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	:	
III.	I understand that the Sponsor of the clinical trial, others working on the Sponsor behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	:	
IV.	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	:	
V.	I agree to take part in the above study.	:	

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

_____

Date:____/____/_____

Signatory's Name:_____

Signature of the Investigator:_____

Date:____/____/_____

Study Investigator's Name:_____

Signature of the Witness:_____

Date:____/____/_____

Name of the Witness:_____

Copy of the Patient information Sheet and duly filled Informed consent form shall be handed over to the Subject his or her attendant.

ANNEXURE 12: STUDY MONITORING VISIT REPORT FORM

Protocol Number and Title	**:**	
Principle Investigator	**:**	
Institute/Department	**:**	
Type of Study	**:**	☐ Investigator Initiated ☐ Pharma ☐ Thesis
IEC, DUPMCH Approval Date	**:**	
Site Initiation Date	**:**	
Study Status	**:**	☐ Ongoing ☐ Completed ☐ Follow-up ☐ Suspended ☐ Terminated ☐ Closed ☐ Closed Prematurely
If the study is Suspended/Terminated/Closed Prematurely, Kindly provide reason:_____		
Subject Recruitment Status	**:**	
Total Number of Patients Screened	**:**	
No. Patients Screen failed	**:**	
No. of Patient Randomized	**:**	
No. of Active Patients in the study	**:**	
No. Of Patients completed the study	**:**	
No. of drop-out patients	**:**	
No. of patients who withdrew consent	**:**	
No. of Patients Withdrawn by PI	**:**	
If the subject is Withdrew consent or Withdrawn by PI, state the reason:_____		
Duration of Study	**:**	
Date of Monitoring Visit	**:**	

Reason for Monitoring	:	☐ Routine ☐ For Cause (State Reason) ☐ SAE reported ☐ Protocol Violation/Deviation ☐ Other _____
Was Monitoring done previously for this study?	:	☐ Yes ☐ No If Yes, date of last monitoring_____
Are the facilities appropriate?? ☐ Yes ☐ No	:	Comment:
Are Informed Consent of Recent Version used? ☐ Yes ☐ No	:	Comment:
Is the used ICF approved by IEC, DUPMCH? ☐ Yes ☐ No	:	Comment:
Whether consent has been taken from all patients? ☐ Yes ☐ No	:	Comment:
Whether appropriate vernacular consent has been taken? ☐ Yes ☐ No	:	Comment:
Are protocols of recent version used? ☐ Yes ☐ No	:	Comment:
Is it approved by IEC? ☐ Yes ☐ No	:	Comment:
Any Adverse event found? ☐ Yes ☐ No	:	Comment:
Was the SAE informed to IEC within 24 hours of occurrence, if any? ☐ Yes ☐ No	:	Comment:

Has Any death occurred?	:	Comment:

☐ Yes ☐ No		
Any protocol Non-Compliance/Violation observed? ☐ Yes ☐ No	:	Comment:
Are all Case Record forms up to date? ☐ Yes ☐ No	:	Comment:
Are Storage of data and investigational products are secured properly with restricted access? ☐ Yes ☐ No	:	Comment:
Are Investigational product dispensing and accountability correct? ☐ Yes ☐ No	:	Comment:
Is Investigational product stored properly at correct temperature? ☐ Yes ☐ No	:	Comment:
Are there any changes in study personnel? ☐ Yes ☐ No	:	Comment:

Number of participants monitored during this visit?

Duration of the visit?

How well are participants protected? ☐ Good ☐ Fair ☐ Not Good

Any other Relevant Observations:

Comments of the monitor:

Duration of Visit:___ Hours **Starting from:** **To:**

IEC, DUPMCH Monitoring Team	**Name**	**Sign and Date**
1		
2		
3		
4		
Present Study Team Members	**Name**	**Sign and Date**
1		
2		
3		

ANNEXURE 13: FORMULAE TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF CLINICAL TRIAL RELATED INJURY OR DEATH

1. **Formula in case of clinical trial related death:**
   Compensation = (B x F x R)
   / 99.37 Where,
   B = Base amount (i.e. 8 lakhs)
   F = Factor depending on the age of the trial subject as per table given on page no(based on Workmen Compensation Act)
   R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

   (a) 0.5terminallyillpatient(expected survival not more than(NMT)6months)
   (b) 1.0 Patient with high risk (expected survival between 6to24months)
   (c) 2.0 Patient with moderate risk
   (d) 3.0 Patient with mild risk
   (e) 4.0 Healthy Volunteers or trial subject of no risk.

   However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs should be given.

2. **Formula in case of clinical trial related injury (other than death):** For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following squeals other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

   i. **A permanent disability:** In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

   The quantum for less than 100% disability will be proportional to the actual percentage
   disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

Where:

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

ii. **Congenital anomaly or birth defect:** The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Stillbirth;
(b) Early death due to anomaly;
(c) No death but deformity which can be fully corrected through appropriate intervention;
(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

iii. **Chronic life-threatening disease; and**

iv. **Reversible SAE in case it is resolved**

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalization of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,

W = Minimum wage per day of the unskilled worker
(in Delhi) N = Number of days of hospitalization

Factor (F) for calculating the amount of compensation

Age	Factor
Not more than...	
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52

45	**169.44**
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

ANNEXURE 14: STUDY PROGRESS REPORT

Project Title Staff / Student Project

1. Approval No.	**:**	
2. Principal Investigator	**:**	
3. Department	**:**	
4. Guide/Co-Investigator	**:**	
5. Department	**:**	
6. Time Since IEC Approval	**:**	
7. Status of Research	**:**	
8. Report of the work done since its inception with particular emphasis on the following	**:**	
• Material & Methods	**:**	
• Material Procedure: Yes /No	**:**	
• Permission Procured: Yes /No	**:**	
• Funding Status: Applied / Procured / NA, give details	**:**	
9. Total Participants / Sample entered / Consented/prepared	**:**	_____
10. Sample size achieved	**:**	
11. Participants Withdrawn from the Studies	**:**	Yes / No, if Yes give details _____
12. Data Collection	**:**	Yes / No / Partially Completed
13. Data Analysis	**:**	Yes /No

Principal Investigator Co-Investigator/Guide

Date: Date:

14. Conclusions and Major results Derived

15. Serious Adverse Event if any with details

16. Problems Encountered Solutions

17. Manuscript Writing: In Progress/Completed

18. List of research publications and paper based on work done of project

19. Remarks of the Guide : Satisfactory / Not Satisfactory

20. On completion of the research please provide the following

A brief abstract describing the study.
Details of unanticipated problems involving risk to the participants or other since beginning of the project and measures employed.
Blank copies of all current consent / Assent forms.

21. Undertaking:

21.1 I /We, the undersigned, give an undertaking to the following effect with regard To (STUDYTITLE)_____

_____

_____

agree with the above information given to the best of my/our knowledge, and does not infringe upon any, copyright , property, or personal right of any third party.

_____

_____

Principal Investigator
Date:

Co-Investigator/Guide
Date:

ANNEXURE 15: CONFLICT OF INTEREST DISCLOSURE FORM

I wish to inform_____Interest that I hold under the categories noted. **The conflict of interest** may be considered potential or actual when exercising decisions and actions in my role as a voting member within the IEC, DUPMCH.

Conflict of Interest

A conflict of interest exists in any situation when a person has a financial interest, a private, personal or familial interest, a business interest sufficient to influence, or appear to influence, the impartial exercise of duties or professional judgments.

Please tick the categories that apply to your area of conflict of interest with name of service below:

Conflict of Interest Definitions	✓
Financial Interest	
The term financial interest means anything of monetary value, including but not limited to	
• Salary or payment for services (for example: consulting fees and honoraria);	
• Equity interests (for example shares, share options and other owner ship interests);	
• Gifts;	
• Allowances, forgiveness of debts, interests in real estate, or personal property, dividends, rents, capital gains; and	
• Intellectual property rights (for example: patents, copyrights and royalties from these rights).	
Personal Interest A staff member has a personal interest in a matter if his or her spouse or partner, or other person in his or her family, or person with whom there is a close friendship, could be advantaged or disadvantaged, by any decision that the member either can make, or does not make, or is in a position to influence.	

Business Interest	
A member will have a business interest in a company seeking to do research at DUPMC if he or she;	
• Is a director of the Company:	
• Is an owner of, or partner in the Company:	
• Has a significant shareholding (equal to or greater than 20% shareholding) in the Company:	
• Has a close personal or familial relationship with a person who is an owner or partner, or significant shareholder in the Company.	
Please detail the Conflict of Interest you wish to disclose:	
Please detail action you propose to reduce, mitigate, or eliminate the conflict of interest:	

Name of the IEC, DUPMCH Member (please print)	**Role in the Committee**
Signature	**Date**
Proposed action to address Conflict of Interest. **(This Section to be completed by Chairperson of the IEC, DUPMCH)**	

Approved action:	
Declined action (and reason for declined):	
Alternative action required to manage conflict of interest (detail below):	
Name of the Chairperson	
Signature of the Chairperson	**Date**

Copy to the member disclosing conflict of interest. Original is to be maintained by IEC, DUPMCH office.

ANNEXURE 16: IEC, DUPMCH SELF-ASSESSMENT FORMAT

Sr. No	Item Description	Yes	No	Don't Know	Remarks if any
	EC as a whole				
1	Does the IEC, DUPMCH policy describe the procedure of selecting the members?				
2	Is there a specified term described to hold the Appointment for its member mentioned in the policy?				
3	Does every meeting of IEC, DUPMCH have the complete quorum as specified?				
4	Is the Chairperson of IEC, DUPMCH a non-affiliated member of your organization?				
5	Does IEC, DUPMCH describe the resignation procedure of its member?				
6	Does IEC, DUPMCH obtain the confidentiality agreement from members at the time of induction?				
7	Does IEC, DUPMCH Maintain the list of their members with their updated CVs?				
8	Does IEC, DUPMCH hold a dedicated office with required infrastructure and staff for its functioning?				
9	Does IEC, DUPMCH organize the training programme to update the knowledge and functioning of its members?				
10	Does IEC, DUPMCH have process to eliminate Conflict of Interest?				
11	Does IEC, DUPMCH SOP contain the specific scope, Objectives, activities, organization, infrastructure and funding aspects?				
12	Is your IEC, DUPMCH SOP regularly revised?				
13	Is functioning of IEC, DUPMCH strictly based on SOP mentioned?				
14	Does IEC, DUPMCH have specified submission guidelines made available to PI for their study protocols?				
15	Is there a specified format for proposal submission as per IEC, DUPMCH guidelines?				

16	Does IEC, DUPMCH involves in registration of trials and biomedical and health research with CTRI and CDSCO?				
17	Does IEC, DUPMCH have specified ICF and PIS formats?				
18	Does IEC, DUPMCH SOP specify the fee structure for the trials submitted?				
19	Does IEC, DUPMCH maintain the records of Minutes of the Meetings?				
20	Is there a fixed schedule of periodic meetings & are the records of attendance for the same maintained?				
21	Is the proposal submitted by PI checked for its Completeness along with the essential annexure attached duly signed by P.I. with date?				
22	Is IEC, DUPMCH strict with the submission of amendments by the PI?				
23	Does IEC, DUPMCH monitor/inspect/Audit the trials conducted as mentioned in SOP?				
24	Does IEC, DUPMCH SOP mention about Periodic Progress and Site Visits to monitor the trials?				
25	Is IEC, DUPMCH SOP based on ICH-GCP E6 (R_2), New Drugs and CT Rules 2019 and ICMR 2017 guidelines?				
26	Is IEC, DUPMCH an independent body?				
27	Does IEC, DUPMCH SOP address the guidelines to be followed for research in vulnerable population?				
28	Does IEC, DUPMCH have Soft Copy and Hard Copy of the records in its office?				
29	Does the IEC, DUPMCH SOP mention about approval and completion of the project?				
	For Individuals				
1	Do you regularly attend IEC, DUPMCH meetings?				
2	Do you know your role in IEC, DUPMCH?				
3	Do you actively involve yourself in review process of protocols by IEC, DUPMCH?				
4	Do you prepare for IEC, DUPMCH meeting prior i.e. with reading documents etc.?				
5	Do you feel that you could improve with better involvement?				

ANNEXURE 17: CHECKLIST FOR CLINICAL TRIAL DOCUMENTS SUBMITTED FOR IEC, DUPMCH REVIEW

(14 hard copies and a CD of all documents listed below)

Protocol Title:	
Principal Investigator:	
Type of Submission	Initial/Amendment
IEC, DUPMCH Submission Number and Date	

SR. NO	MANDATORY DOCUMENTS	YES	NO	NA
1	IEC, DUPMCH Processing Fee			
2	Submission Covering Letter duly signed by the Principal Investigator			
3	Study Protocol			
4	Investigator Brochure (IB)			
5	Patient Information Sheet (PIS) & Informed Consent Forms (ICFs) in English, Hindi and arati (and if require any other language)			
6	Translational Certificates for Hindi and arati (Back Translation certificate whenever applicable)			
7	Final Version of Case Record Form (CRF)			
8	Recruitment Procedure; advertisement, notices (if applicable)			
9	Patient Instruction card, diary, etc. (if applicable)			
10	DCGI Approval Letter/DCGI Submission Letter			
11	Insurance Policy and Certificate/Indemnity certificate (If applicable)			
12	Final Version of Clinical Trial Agreement (CTA)/Memorandum of Understanding (MoU)			
13	Undertaking by the PI			

SR. NO	MANDATORY DOCUMENTS	YES	NO	NA
14	Brief CV, MRC and GCP certificate of Investigator duly signed and dated			
15	Clinical Trial Registry – India (CTRI) Registration Certificate			
Documents Submitted: Complete Incomplete will submit on ……				
Remarks, if any:				
Receiver Name, Sign & Date: **(IEC, DUPMCH Secretariat)**				

+

ANNEXURE 18: TEMPLATE FOR INFORMED CONSENT DOCUMENT FOR PARTICIPANTS' PARENTS FOR RESEARCH INVOLVING CHILDREN/MINORS

(This template is for either clinical trials or clinical research)
(Language used throughout form should be at the level of a local student of class 6th/8th)

[YOUR INSTITUTIONAL LETTERHEAD]

[Informed Consent Form for Parents of Children (*having X condition/with Y disorder etc. as applicable as per your research*)]

Name the group of individuals for whom this parental consent is written.

[Name of Principal Investigator]

[Name of Organization]

[Title of the Research Study]

[Participant Initials/ Code]

This Informed Consent Form has two parts:

Information Sheet (to share information about the study with you)

Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

1. **Introduction**
2. **Purpose**
3. **Type of Research Intervention if any**
4. **Why your child is chosen for the study?**
5. **Is your child's participation compulsory?**

(Include the following section only if the protocol is for a clinical trial:)

6. **Information on the Trial Drug [Name of Drug]**

---

7. **Procedures and Protocol**

Unfamiliar Procedures: (Explanation about randomization, blinding, placebo, rescue medications/therapy, allocation concealment etc. if applicable)

Process Steps to be followed: (Explanation about biopsy, blood sample collection, anesthesia requirements etc, infection control practices etc.)

8. **How long would the study continue?**
9. **What side effects could be foreseen to happen to your child in this study?**
10. **What if something goes wrong with your child?(Risks)**
11. **What Discomforts may your child feel during course of the study?**
12. **(Explain about the possible disturbance in behavior that may arise due to needle prick etc.)**
13. **What Benefits would your child avail?**
14. **What all reimbursements would be provided to your child?**
15. **Is your child's data Confidential?**
16. **How would the results of the study be communicated?**
17. **Could your child withdraw from the study in between?**
18. **What are alternatives if your child does not participate?**
19. **Whom to Contact?**

PART – II Informed Consent Form for Participant's Parent (ICFP)

(Tick √ or × in boxes against each point).

I have been invited to have my child participate in research of (Title of Study)	
I have read the foregoing information, or it has been read to me.	
I have had the opportunity to ask questions about it and any questions that I have asked	
I have been answered to my satisfaction.	
I consent voluntarily for my child to participate as a participant in this study.	

Print Name of Participant:_____
Print Name of Parent or Guardian:_____
Signature of Parent or Guardian:_____
Date (DD/MM/YYYY):_____

If illiterate

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

Print name of witness: _____ AND Thumb print of parent
Signature of witness: _____
Date:_____

Statement by the researcher/person taking consent
(Tick √ or × in boxes against each point).

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands the Study procedures.	
I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability.	
I confirm that the individual has not been coerced into giving consent for his/her child's participation, and the consent has been given freely and voluntarily.	

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent:_____
Signature of Researcher /person taking the consent: _____
Date (DD/MM/YYYY):_____
An Informed Assent Form will/will not be completed

ANNEXURE 19: TEMPLATE FOR INFORMED ASSENT DOCUMENT FOR RESEARCH INVOLVING CHILDREN/MINORS

[Informed Assent Form for Children_____]

[Name of Principle Investigator]:
[Name of Organization]:
[Title of Research Study:]
[Subject Initials/Identifier/Code]:

Part 1: Information Sheet

Introduction:

Purpose: Why this research? :
Why are you selected? :
Is it compulsory to do this? :
I have checked with the child and they understand that participation is voluntary --- (initial of researcher)(to be filled by researc | | |

(Applicable to Clinical Trials Only)
Information on the Trial Drug

[Name of Drug]: What is this drug and what do you know about it?

Include the following section only if the protocol is for a clinical trial:

1) Give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) Provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial.

……
…

Procedures: What is going to happen to you?
I have checked with the child and they understand the procedures---------- (initial of researcher)(to be filled by investigator) | | |
Risks: Is this bad or dangerous for me?
Explain any risks using simple, clear language.

Discomforts: Will it hurt?
If there will be any discomforts state these clearly and simply. State that they (children) should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

I have checked with the child and they understand the risks and discomforts---------- (initial of researcher)(to be filled by investigator) | | |

Benefits: Is there anything good that happens to me?
Describe any benefits to the child.

I have checked with the child and they understand the benefits---------- (initial of researcher)(to be filled by investigator) | | |

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research? These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

Confidentiality: Is everybody going to know about this?
Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

Compensation: What happens if I get hurt?
Describe to the ability of the child to understand and explain that parents have been given more information.

Sharing the Findings: Will you tell me the results?
Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly,
i.e. in a book, journal, conferences, etc.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

Whom to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

I understand that this research include
(add experimental aspects i.e. needle prick, survey, biopsy, lab investigations etc., details about follow-up visits, maintenance of patient diary by self/parents)

I have read this information (or had the information read to me)

I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below.
_____(Initial led by child/minor)

<u>Only if child assents</u>:

Print name of child:_____
Signature of child: _____
Date:_____

***If illiterate**:*
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, 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 assent form to the child, and the individual has had the opportunity to ask questions.

I confirm that the individual has given consent freely.
Print name of witness (not a parent):_____ AND Thumb print of
Participant Signature of witness: _____
Date: _____

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions.

I confirm that the individual has given assent freely.

Print name of researcher: _____
Signature of researcher: _____
Date: _____

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 child understands that why and how the study would be done and his/her role as a subject.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her 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 assent form has been provided to the participant.

Print Name of Researcher/person taking the assent & Signature

_____

- ✓ **Copy provided to the participant_____(initialed by researcher/assistant)**
- ✓ **Parent/Guardian has signed an informed consent__Yes___No___(initialed by researcher/assistant)**

ABBREVIATIONS

SOP	Standard Operating Procedure
DUPMCH	Dr. Ulhas Patil Medical College and Hospital
IEC, DUPMCH	Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital
ICMR	Indian Council of Medical Research
HRRP	Human Research Review Panels
IEC	Institutional Ethics Committee
CV	Curriculum Vitae
MoU	Memorandum of Understanding
ICD	Informed Consent Document
CTA	Clinical Trial Agreement
NGO	Non Governmental Organization
MRC	Medical Research Council
CTRI	Clinical Trials Registry-India
CDSCO	Central Drugs Standard Control Organization
PIS	Patient Information Sheet
ICF	Informed Consent Form
AV	Audio Visual
EC	Ethics Committee
CoI	Conflict of Interest
AE	Adverse Event
SAE	Serious Adverse Event
CT	Clinical Trial
CRF	Case Report Form
PI	Principal Investigator
ICH-GCP	International Conference on Harmonization- Good Clinical Practice
DCGI	Drug Controller General of India
IW	Impartial Witness
LAR	Legally Acceptable Representative