VELAMMAL MEDICAL COLLEGE
HOSPITAL AND RESEARCH INSTITUTE
MADURAI - 625009

3.3.1

Code of Ethics of Research signed by the Dean

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Institutional Ethics Committee

Standard Operating Procedures (SOPs)

Version 3.0

(updated on 22/06/2022)

(Hereinafter referred to as **IEC of VMCHRI** throughout this document)

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Institutional Ethics Committee of

Velammal Medical College Hospital and Research Institute, Madurai

Standard Operating Procedures

1. Preamble and Functional basis

The importance of ethical conduct of research involving human subjects has been recognized worldwide.

The first international treatise on ethics of research involving human subjects was published in 1947 as the Nuremberg Code. The World Medical Association formulated guidelines for conducting research on human subjects in 1964, termed as the Declaration of Helsinki. This has undergone multiple revisions, the latest version being released in 2013 at Fortaleza, Brazil. Other internationally recognized works and guidelines towards ethical conduct of research on human subjects include the Belmont Report of 1979, the Common Rule in 1991 (revised in 2017), the Good Clinical Practice Guidelines E6 (R1) by the International Conference on Harmonization (ICH-GCP guidelines) in 1996 (revised as E6 (R2) in 2016),), the Council for International Organizations of Medical Sciences (CIOMS), Geneva (2002, revised in 2016), and the UNESCO's Universal Declaration on Bioethics and Human Rights (2005).

In India, the Indian Council of Medical Research (ICMR) released a policy statement in February 1980 consisting of the ethical considerations involved in research on human subjects as guidelines for conduct of clinical research in India. These guidelines were called as the ICMR guidelines, and revisions to the same were released in 2000, 2006, and the latest one in the year 2017 (National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017). Meanwhile, the Central Drugs Standard Control Organization (CDSCO) also released the Indian Good Clinical Practice Guidelines (2001) for clinical trials. The Schedule Y of the Drugs and Cosmetics Act, 1940, was revised in the year 2005 with several amendments in the Rules under Drugs and Cosmetics Act in the year 2013. The ICMR, jointly with the Department of Biotechnology (DBT) released the Guidelines for Stem Cell Research and Therapy in 2007, which were further revised in 2013 and 2017.

The Institutional Ethics Committee (IEC) of Velammal Medical College Hospital and Research Institute (VMCHRI) has been formulated keeping in mind the provisions and regulations of the above-mentioned guidelines.

2. Basic Responsibilities

The basic purpose of the IEC is to safeguard the interests of the trial subjects. These interests may include safety, confidentiality, and well-being. Special attention is to be paid when a research involves vulnerable population.

The functioning of IEC should be in the background of the 12 general ethical principles, as mentioned in the 2017 ICMR guidelines:

1. ***Principle of essentiality:*** *The use of human participants is considered essential for the proposed research only after due consideration of all alternatives in the light of existing knowledge. This should be duly vetted by an ethics committee (EC) independent of the proposed research.*

2. ***Principle of voluntariness:*** *Voluntary participation of the subject is paramount. The informed consent process is vital for any research involving human subjects. Respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, should be upheld.*
3. ***Principle of non-exploitation****: Research participants should be equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Informed consent process should be clear-cut with respect to non-exploitation of trial subjects. Sufficient safeguards to protect vulnerable groups should be ensured.*
4. ***Principle of social responsibility****: The research should be planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.*
5. ***Principle of ensuring privacy and confidentiality****: To maintain privacy of the potential participant, his/ her identity and records should be kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the IEC or other suitable authorities for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.*
6. ***Principle of risk minimization****: Due care should be taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs. Patient information sheet should include all possible risks and compensatory measures of a particular research, in a language that can be understood by the intended participants of the research.*
7. ***Principle of professional competence:*** *The research should be planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.*
8. ***Principle of maximization of benefit****: Due care should be taken to design and conduct the research in such a way that the benefits of the research are maximized directly or indirectly to the research participants and/or to the society.*
9. ***Principle of institutional arrangements:*** *Institutions where the research is being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.*
10. ***Principle of transparency and accountability:*** *The research plan and outcomes of the research should be brought into the public domain through reports, scientific publications, presentations in conferences and other relevant means, while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/ audit.*
11. ***Principle of totality of responsibility:*** *All stakeholders involved in research should be responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.*

12. ***Principle of environmental protection****: Researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.*

3. Composition and Functioning of the IEC

The Dean, VMCHRI, Madurai, has formulate the IEC of VMCHRI.

3.1. Conditions of Appointment

- The IEC shall be multi-disciplinary and multi-sectoral. There shall be adequate representation of age and gender.
- Preferably 50% of the members shall be non-affiliated or from outside the institution.
- There shall be a minimum of 7 and a maximum of 15 members in the IEC. A minimum of five members should be present to meet the quorum requirements.
- The EC shall have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution
- For maintaining independence of the IEC, the Chairperson of the IEC shall be from outside the Institution. Also, the Dean of VMCHRI shall not be the part of IEC, but should act as an appellate authority to appoint the committee or to handle disputes.
- The Member secretary may be preferably a pharmacologist.
- All the technical members (Clinicians and Basic Medical Scientists) shall possess postgraduate qualifications in their respective fields.
- All members shall be GCP trained and possess valid GCP training certificates. The members shall also keep themselves updated to the modifications pertaining to clinical research regulations including ICMR guidelines, Schedule Y, and GCP guidelines.
- The IEC shall, if required, consult subject experts or representatives from special patient groups (eg patients with HIV, genetic disorders, cancers, etc) to resolve conflicts or to arrive at decisions pertaining to ethical review processes involving special populations. Such members may be invited to attend the IEC meeting to give an expert opinion on a specific proposal, but such members shall not have decision making power/voting rights.
- The Dean shall nominate and invite persons both from the institute and outside the institute for being members of the IEC. Upon acceptance, such persons shall give consent in writing to be a member of the IEC and submit his/her recent curriculum vitae.
- Every member shall, in writing, submit essential undertakings to the IEC, namely, confidentiality agreement, declaration of conflict of interest, and any other such document that the IEC desires.
- A member should attend at least 2 meetings during a calendar year to be eligible for continuation of the membership.
- All members shall strictly maintain confidentiality of all the discussions during the proceedings of meetings.
- All the members of the IEC shall declare Conflict of Interest, if any.
- Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications.

3.2. Terms of Reference of the Committee

- The IEC is constituted and shall be reconstituted or modified as and when required by the head of the institution, i.e., the Dean of VMCHRI.
- The tenure of each member would be three years, at the end of which he/she may be eligible for re-appointment.
- At the end of 3 years, the IEC members shall be required to produce in writing their willingness to continue as members of the IEC.

- Any member can resign from the committee giving proper reason in writing to do so. Such resignation will be considered in next meeting of the IEC. If it is accepted, the resulting vacancy would be filled in by appointing a suitable person belonging to the same category.
- Similarly, a member can be replaced in event of death or any other valid reason.
- The IEC would meet at least 4 times in a year, preferably once in each quarter. Additional meetings may be held as and when required.
- Notice of the meeting will be served in 10 working days prior to the date of the meeting to all IEC members in case of regular meetings and 5 working days prior in case of Emergency meeting.

3.3 Resignation / Replacement procedure: The members who have resigned may be replaced at the discretion of the Dean,VMCHRI. IEC members who decide to resign must provide the Dean, VMCHRI, and Chairperson, IEC, the written notification/email of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Dean,VMCHRI, would appoint a newmember, falling in the same category of membership e.g. NGO representative with NGO representative. Recommendations may be sought from the resigning member. Appointments may be made in consultation with the Member Secretary and /or Chairperson.

3.4 Essential Qualifications of Members of IEC

No	Member	Qualifications
1	Chairperson (Non-affiliated)	• Should not be affiliated to VMCHRI • Should be a well-respected person from any background • Preferably having prior experience of having served in an EC
2	Member-Secretary (Affiliated)	• Should be a staff member of VMCHRI • Shall be preferably a pharmacologist • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution
3	Basic Medical Scientists (Affiliated/ Non-affiliated)	• Medical or non-medical person with adequate post-graduate qualifications in basic medical sciences • In case of IEC reviewing clinical trials with drugs, one of the basic medical scientists should preferably be a pharmacologist
4	Clinicians (Affiliated/ Non-affiliated)	• Should be individual/s with recognized post-graduate medical qualification, expertise and training
5	Legal Expert (Affiliated/ Non-affiliated)	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.
6	Social scientist/ philosopher/ ethicist/ theologian (Affiliated/ Non-affiliated)	• Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

7	Layperson representative (Non-affiliated)	• Literate person from the public or community • Has not pursued a medical science/ health- related career in the last 5 years • A representative of the community from which the study participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities

4 Roles and Responsibilities of Members of IEC

No	Member	Roles and Responsibilities
1	Chairperson (Non-affiliated)	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of the Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek conflict of interest declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2	Member-Secretary (Affiliated)	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
3	Basic Medical Scientists (Affiliated/ Non-affiliated)	• 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, pharmacologist to review the drug safety and pharmacodynamics.
4	Clinicians (Affiliated/ Non-affiliated)	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	Legal Expert (Affiliated/ Non-affiliated)	• Ethical review of the proposal, informed consent form along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6	Social scientist/ philosopher/ ethicist/ theologian (Affiliated/ Non-affiliated)	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/ participant/ societal/ community representative and bring in ethical and societal concerns.
7	Layperson representative (Non-affiliated)	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any

5 Quorum for the Meeting

1. A minimum of five members present in the meeting room.
2. The quorum should include both medical and non-medical, or both technical or/and non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
6. No decision is valid without fulfilment of the quorum.

4] Procedure:

4.1 Documents to be submitted for consideration of a Research Project:

4.1.1 Appendix I, lists all the documents that a Principal Investigator needs to submit to the IEC for consideration of the research project, along with a covering letter to the Chairperson/Member Secretary.

4.1.2 Documents should be submitted to the office of the IEC, i.e. department of Pharmacology, VMCHRI, Madurai-9 on or before the scheduled date of submission in a durable new plastic coated file.

4.1.3 A dissertation or thesis project should be submitted only after approval of the institutional thesis committee.

4.2 Processing of research Projects:

- The member secretary shall assign a unique code or number to each proposal and check it for completeness.
- Documents that need enough time for the IEC members' review, i.e. Complete Study Protocol, ICF with translations and Case Record Form (CRF) must be submitted within scheduled time.
- As regards other documents to be submitted, incomplete documents will not be accepted. If any document as per the requirement is missing/incomplete, the ember-secretary shall inform the PI and notify it in writing. If such information is sent by phone, SMS, fax or email, it shall be documented.
- Compliance to such fulfilment of required documents must be ensured at least 2 working days prior to the date of the meeting.

4.3 Review Meeting:

- The member-secretary shallconvene a meeting of the Committee in consultation with the Chairperson after confirmation of presence of members essential to the quorum.
- If a proposal requires urgent review, an Emergency meeting may be convened with justification and in consultation with the members as above.
- The quorum for emergency meeting shall be the same as for the regular meetings.
- Subject expert may be invited to offer their views based on the requirement of the research area, e.g. HIV, AIDS, genetic disorders etc. in case of specific project. But no such expert shall have voting rights.

- **Whenever projects involving vulnerable population** [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 others incapable of personally giving consent] are to be considered, special expert invitee to safeguard the interest of that population is to be invited and/or the project would be sent to such an expert for opinion by the decision of the Ethics committee keeping confidentiality agreement in place.

- Specific patient groups may also be represented in the ethics committee as far as possible.
- The member-secretary shall maintain an attendance log for each meeting.

- The Principal Investigators or a suitable member of his team should note the date, time and venue of the meeting and make themselves available for offering clarifications, if any, during review of the proposal at the time of meeting as well as for discussions with committee members or subcommittees as and when required.
- PG teacher of the student whose protocol is being considered should note the date, time and venue of the meeting and make themselves available for offering clarifications, if any, during review of the proposal at the time of meeting as well as for discussions with committee members or subcommittees as and when required.
- The Chairperson shall preside over the meeting and conduct the proceedings. If he is unable to attend, he shall preferably in writing nominate another member to act on his behalf.
- Every attempt shall be made to reach a consensus on each proposal reviewed. However, if this fails, the proposal shall be put to vote and the decision shall be recorded with the number of votes for and against. In case there is a tie, the Chairperson may either cast a deciding vote or postpone the decision to the next meeting pending further inquiry into the merits of the proposal and an attempt to reach a consensus.
- Only the members who attend the meeting and take part in the deliberations shall vote on the proposal(s).
- Only those IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial related matter. (*vide* conflict of interest).
- The decision on each proposal shall be minuted and communicated to the PI within two weeks after the meeting.
- **Conflict of interest :** A set of conditions in which professional judgment concerning a primary interest like patients welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like nonfinancial (personal, academics or political) or financial gain; as decided by majority of IEC members in the meeting.
- There should be no conflict of interest as regards any proposal for any IEC member. However if at all there is a conflict of interest, the concerned member/s shall voluntarily declare the conflict of interest and withdraw from the IEC meeting while making a decision on that proposal. This may be indicated in writing to the Chairman prior to the review and be recorded in the minutes. The member/s who declare/s such conflict does not participate in the discussion except for clearing doubts and does not vote as regards approval/disapproval of that project.

4.4 Appeal

4.4.1 If a proposal is rejected by the IEC, the PI may appeal within 12 weeks for a fresh review after providing the justification for such reconsideration.

4.4.2 If a rejected proposal is not submitted for reconsideration within 12 weeks, it has to be submitted as a fresh proposal on charge of fees as stipulated under fees.

4.5 Other provisions

4.5.1 The Chairperson or his nominee may approve a project without calling a meeting for studies of the following nature or the like:

i. The project involves absolutely no risk to the subject, i.e., retrospective studies, epidemiological studies, non-interventional studies, processing of samples already sent to the lab, etc.

ii. For all projects, any amendments in the Protocol or other document submitted, which have been reviewed earlier, and are of an administrative nature, or imply a change that does not affect the rights, safety and well-being of the subjects, on payment of the prescribed fees.

iii. The protocol reviewed in an earlier meeting has been considered approvable with suggested amendments, and has now been amended accordingly.

4.5.2 To avail the benefit of the above provisions, an undertaking has to be submitted by the PI specifying the category under which consideration for approval is sought.

4.6 Responsibilities of the Principal Investigator (PI):

The responsibilities of the PI are as under:

- A six monthly detailed report of the progress of the clinical trial/study.
- A written report of each serious or unexpected (as per the Investigator's Brochure) adverse event with regard to the study within 24 hours of occurrence of the serious adverse event.
- A written report of each non-serious adverse event (as per the Investigator's Brochure) with regard to the study within 7 days of occurrence of the adverse event, in the standard format.
- To inform, giving justification, and seek approval from the IEC pertaining to any amendment/revision to the protocol, before it is implemented.
- To inform the IEC of study completion or discontinuation, or any important events occurring in the study at other sites in case of a multicentric study, with reasons for the same.
- To submit justification for approval to restart studies discontinued earlier by the IEC and not restart it before such approval.
- To submit to the IEC a final report on the study, on its completion, closure or termination.
- The PI or Co-investigator of a new research project may be required to attend the IEC meeting to answer any queries etc. pertaining to their project. He/she will retire from the meeting after the presentation is over and not participate in the other deliberations of the IEC meeting or vote.

4.7 Ongoing review:

The progress of approved research projects will be reviewed by the IEC at six monthly intervals. Reports of SAE, or any other new information that has been brought to the attention of the IEC, will be considered, especially if it requires an amendment of the protocol or termination of the study.

4.7.1 SAE reporting: Cases of SAE, other than deaths, shall be examined as under:

(A) As defined under rule 21(b) of Gazette of India dated 30 January 2013, the sponsor or his representative, whomsoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on SAE, after due analysis, to the Licensing Authority, Chairman of the IEC and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the SAE.

(B) The IEC shall forward its report on the SAE, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his representative, whomsoever had obtained permission from the Licensing Authority as defined under rule 21(b) of Gazette of India dated 30 January 2013 for conducting the clinical trial with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the SAE or death

4.7.2 Cases of SAE of death shall be examined as under:

(A) As defined under rule 21(b) of Gazette of India dated 30 January 2013, the sponsor or his representative, whomsoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on SAE of death, after due analysis, to the Licensing Authority, Chairman of the IEC and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the SAE.

(B) The IEC shall forward its report on the serious adverse event of death, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his representative, whomsoever had obtained permission from the Licensing Authority as defined under rule 21(b) of Gazette of India dated 30 January 2013 for conducting the clinical trial with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of the death

5] Policy regarding training of Existing or New IEC members:

Training programmes are regularly organized by various competent and recognized agencies/ institutions for training of IEC members. Members of IEC are encouraged to attend such programmes and update themselves about recent advances in ethical considerations regarding biomedical research. Our institution also conducts such programs. This IEC undertakes to fulfil requirements as regards training of the members and other research personnel from time to time as per government regulations, guidelines and directives.

6] Record Keeping:

6.1 All documentations and communications of the IEC shall be dated, filed and preserved according to the SOP (*vide infra*). Strict confidentiality shall be maintained during access and retrieval process as regards any of these documents.

Records shall be maintained for the following:

(a) Constitution and composition of the IEC
(b) The CVs of all the committee members
(c) SOPs followed by the committee
(d) National and International Guidelines e.g. ICH-GCP guidelines, ICMR guidelines, Schedule Y, Declaration of Helsinki and other similar essential documents.
(e) Copies of the Protocol, data collection formats, CRFs, investigator brochures, etc., submitted for the review
(f) All correspondence with IEC members and investigators regarding applications, decisions and follow up
(g) Agenda of all IEC meetings
(h) Minutes of IEC meetings with signature of the Chairman and Secretary
(i) Copies of decisions communicated to the applicants
(j) Records of all notifications issued for the premature termination for the study with the summary of the reasons
(k) Final report of the study including microfilms, CDs and video recordings or in any other similar formats

All records shall be safely maintained after the completion of the study for not less than 5 years from the date of completion or termination of the trial and 10 years in case of compensation claim.

6.2 Financial records

The amount deposited in the account ofIEC, the record of advance taken from Res. Soc. & expenditure. The accounts of IEC shall be reported in each IEC meeting and shall be available for audit purpose to any member of IEC or an authorized competent officer permitted by Dean,VMCHRI, Madurai.

With due permission from higher authorities, a separate account will be opened in the name of IEC of VMCHRI, Madurai, for the necessary financial transactions. All accounts will be looked after by responsible officers and members as signatories.

This statement of income and expenditure is presented in every meeting for information and approval. It will also be regularly audited annually by designated auditors. Nomination of auditors would be by resolution and approval in the IEC.

7. Monitoring and surprise checks of Approved studies:

IEC will arrange for regular monitoring as well as surprise checks regarding studies approved by it. Such checks, inspections, or audits will be carried out by members of IEC or non- member experts suitably chosen by IEC.

8. Processing Fees of IEC:

The processing fee for reviewing a research proposal will be as follows:

8.1

8.1.1 The dissertation research proposals of the institute if submitted within specified time period will be exempted from processing fee.

8.1.2 The research projects of the institute, if not funded, will also be exempted from processing fee.

8.1.3 The research projects funded by Government agencies like ICMR etc. or submitted by IEC, VMCHRI, Madurai will be exempted from processing fee.

8.1.4 If such proposals are submitted after specified time period, a late fee of Rs. 500/- will be charged for the same.

8.1.5 The processing fee is Rs. 500/- per meeting in which amendments are considered.

8.2

8.2.1 The dissertations, research proposals of the other institute/part-time students will be charged one time registration fee of Rs. 5,000/-

8.2.2 If investigator of such a proposal requires a special IEC meeting to be convened for urgent review of the proposal or if such proposals are submitted after specified time period, the fee shall be Rs. 10,000/-

8.3

8.3.1 The research proposals funded by private agencies will be charged one time registration fee of Rs. 15,000/-

8.3.2 If a sponsor requires a special IEC meeting to be convened for urgent review of the proposal or if such proposals are submitted after specified time period, the fee shall be Rs. 20,000/-

8.3.3 The processing fee is Rs. 5000/- per meeting in which amendments are considered.

8.4 Duplicate approval letters for the any proposal will be charged Rs 500/- per application

8.5 If a copy of previously submitted synopsis is required from the IEC, it will be issued only as a soft copy, on payment of Rs. 500/- per synopsis.

The fee should be paid by a Demand Draft in favour of "IEC of VMCHRI, Madurai." and is to be deposited in the Indian Overseas Bank, VMCHRI, Madurai. Account No. ……

The applicants paying any fees by DD should write their names and the name of their respective Departments on the original counter-slip and attach with the proposal of dissertation.

The amount so collected shall be used only for expenditures of IEC of VMCHRI, Madurai.

9. Honorarium and Payments:

The members of the IEC shall be paid an honorarium as per the rates decided from time to time depending on whether the member belongs to institution or is from outside the institution. The consolidated honorarium currently offered per meeting is as specified below, and shall be paid when adequate funds are available.

Institutional Members	Rs. 500/-
Non- Institutional Members	Rs. 2000/-
Office Staff	Rs. 300/-
Cl. IV Staff	Rs. 200/-

The members and the staff shall be reimbursed the out-of-pocket expenses such as travel cost etc, incurred for the purpose of IEC.

It is proposed to offer the honorarium to the expert invitees as well, as per the above schedule.

10. Amendments:

IEC reserves its right to modify, change, include or delete any part or any SOP in its meetings with prior intimation of the same in the agenda, or by circulation giving enough period of time for the members to give feedback.

The IEC undertakes that it will make suitable changes as amended in these SOPs as per scientific, ethical and rational local mandates. Similarly it will accept and adhere to the regulations related to its constitution and function and other amendments by governmental regulatory authorities.

DOCUMENTS FOR RESEARCH PROPOSALS

(NON- DISSERTATION)

For submission of Research Proposal to Institutional Ethics Committee of VMCHRI, Madurai.

1) Cover Page (Appendix 1)
2) Check-list-Enclosures (Non-Dissertation) (Appendix 2)
3) Protocol for clinical trial /Research Proposal (Appendix 3)
4) Inform Consent (Appendix 4)
   - 2.a English
   - 2.b Tamil
   - 2.c Hindi
5) Adverse events (Appendix 5)
6) PI undertaking (Appendix 6)
7) Certificate

Appendix 1

Cover Page

(Research projects – Non-dissertations)

For submission of Research proposal to

Institutional Ethics Committee of VMCHRI, Madurai

1. Full Name of Principal Investigator(P.I.):
2. Names of Co-investigators :
3. Department:
4. College Name &Address :
5. Title of Research Project topic:
6. Name of Funding agency :
7. Starting Month of Project :
8. Durations of Project :
9. Contact phone number of P.I.:

Appendix 2

Check-list –Enclosures

Sr.No.	Content	Enclosed	Remarks
1	One page executive summary sheet of trial Protocol(Title, Name of P.G.Student, Name of P.G.Guide, Name of Department, Name of the Institute, Introduction, Aim & Objectives, Material & Methods, Risks involved & Expected Results)		
2	Trial Protocol : in detail-one copy (Appendix 3)		
3	Case report form, Data Collection Form, Subject Diary Card , Informed Consent Form (English, Marathi, Hindi), Information for Patient (English, Marathi, Hindi), Adverse event monitoring (Appendix 5)		
4	Investigator's Brochure		
5	Package insert/product Information		
6	Proposed methods for Subject recruitment including advertisement (s) etc. proposed to be used for the purpose.		
7	Special contingency policy – Clinical trials : of National Insurance Co. Ltd. No. (Valid from to).		
8	Principal Investigator's current CV.		
9	Investigator's Agreement with the Sponsor.		
10	Investigator's Undertaking (Appendix 5)		
11	Drug Mfg. Lic. No. from Drugs Controller (India) dtd.		
12	Approval /Permission from D.C.G.I.		
13	Approval of EC of the Collaborating Center, (if applicable)		
14	Details of research grant		
15	Any other relevant documents as per as regulatory requirements/guidelines.		
16	Certificate from HOD (Appendix 7)		
17	permission from Dean, VMCHRI, Madurai		

Appendix 3

PROTOCOL FOR CONDUCTING CLINICAL TRIALS:

For submission of Research proposal to

Institutional Ethics Committee of VMCHRI, Madurai.

1] Title Page

2] Table of Contents

- 2.1 Background and Introduction.
- 2.2 Study Rationale

3] Study Objective(s) (Primary as well as secondary) and their logical relation to the study design.

4] Study design

5] Study Population

6] Subject Eligibility

7] Study Assessments

8] Study Conduct

9] Study Treatment

10] Adverse Events

11] Ethical Considerations

12] Study Monitoring and Supervision

13] Investigational Product Management

14] Data Analysis

15] Undertaking by the Investigator

16] Appendices.

Appendix 4

1] Checklist for study Subject's informed consent documents.

1.1 Essential Elements:

a. Statement that the study involves research and explanation of the purpose of the research.
b. Expected duration of the Subject's participation.
c. Description of the procedures to be followed, including all invasive procedures and
d. Description of any reasonably foreseeable risks or discomforts to the subject.
e. Description of any benefits to the subject or others reasonably expected subject should be made aware of this.
f. Disclosure of specific appropriate alternative procedure or therapies available to the subject.
g. Statement describing the extent to which confidentiality or records identifying the subject will be maintained and who will have access to subject's medical records.
h. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).
i. Compensation and/or treatment(s) available to the subject in the event of a trial related injury.
j. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.
k. The anticipated prorated payment, if any, to the subject for participating in the trial.
l. Subject's responsibilities on participation in the trial.
m. 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.
n. Any other pertinent information.

1.2 Additional elements, which may be required.

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.
b. Additional costs to the subject that may result from participation in the 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 subject participating in a clinical trial.

Informed Consent Form to participate in a Clinical Trial.

Study Title: _____

Study Number: _____

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

Date of Birth/Age: _____

		Please initial box (Subject)
i.	I conform that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions.	( )
ii.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	( )
iii.	I understand that the Sponsor of the Clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	( )

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

Appendix 5

Adverse Events

1] Patient Details

2] Suspected Drug(s)

3] Other Treatment(s)

4] Details of Suspected Adverse Drug Reaction(s)

5] Outcome

6] Details about the investigator*

* = Information marked * must be provided.

Appendix 6

UNDERTAKING BY THE INVESTIGATOR

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

2] Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and /or any other statement(s) of qualification(s)

3] Name and address of all clinical laboratory facilities to be used in the study.

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

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

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/favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

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

iv. I agree to inform all 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 GCP 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 and GCP guidelines.

vi. I have read and understood the information in the Investigator's broacher, 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/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions; 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 unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurrence.

xi. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

xii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trails.

8] Signature of Investigator with Name and Date.

InvestigatorsNameSignatureDate

Principal Investigator

Co-Investigator 1

Co-Investigator 2

Appendix 7

CERTIFICATE

Date :

This is to certify that Research Protocol entitled

_____
_____

has been presented, discussed and modified accordingly. Further it is stated that to the best of my knowledge there is no ethical dispute in this research protocol and therefore may be approved by the Institutional Ethics Committee of Velammal Medical College Hospital Research Institute, Madurai.

_____
Signature

Name of Head of Department: _____

Department: _____

Institute: _____

DOCUMENTS FOR DISSERTATION/THESIS

CHECK-LIST ENCLOSURES (DISSERTATION/ THESIS)

For submission of Research proposal to

Institutional Ethics Committee of VMCHRI, Madurai

1] Cover Page (Appendix 1a)

2] Check-List Enclosures (Dissertation)

1. Research Proposal (Appendix 2a)
    - 1. a Part I – General Information
    - 1. b Part II – One page executive summary sheet
    - 1. c Part III - Details of Research Proposal
2. Informed Consent (Appendix 4a)
    - 2. a English
    - 2. b Tamil
    - 2. c Hindi
3. Application for Permission for Animal Experiments.
4. PI undertaking (Appendix 6)
5. Certificate from HOD (Appendix 7)
6. Certificate of approval from Institutional Thesis Committee

Appendix 1a

Cover Page

(for Dissertations)

For submission of Research proposal to

Institutional Ethics Committee of VMCHRI, Madurai

1. **Full Name of PG Student (Start with Surname):**
2. **Department:**
3. **Candidate admitted in the year:**
4. **Course and subject:**
5. **College Name & Address:**
6. **Title of Research Project topic:**
7. **Full name of P.G. Guide:**
8. **Contact phone number of PG Student:**

Appendix 2a

CHECK- LIST ENCLOSURES (DISSERTATION)

PART I

GENERAL INFORMATION

1. **TITLE OF THE PROJECT** :

.

2. **NAME AND DESIGNATION OF** :

   a) **Postgraduate Guide** : .

   b) **Postgraduate Student:**

3. **DURATION OF THE PROJECT** :

a) Period that may be required for data collection :
b) Deadline for collecting data :
c) Period that may be required for analysis of data :
d) Deadline for analysis of data :

4. **DEADLINE FOR SUBMISSION OF THE DISSERTATION TO**

   THE UNIVERSITY :

5. **REVIEW OF PROGRESS** :

Reviews	**1st quarter**	**2nd quarter**	**3rd quarter**
Review of progress of project			
Review of collection of data			
Review of analysed data			

6. **SIGNATURES** :
   a) Postgraduate student :
   b) Postgraduate guide :
   c) Head of dept(Parent/Concerned) , …… , Madurai:
   d) Head of dept , (Other involved)……,Madurai:
   e) Head of dept , (Other involved) ……, Madurai:
7. a) Date of submission to ethical committee :

b) Date of clearance of the committee :

c) Remarks of the secretary :

PART II

One page executive summary sheet of trial Protocol

1) **Title :-**
2) **Name of P.G.Students :-**
3) **Name of P.G. Guide :-**
4) **Name of Department :-**
5) **Name of the Institute :-**
6) **Introduction :-**
7) **Aim &Objectives :-**
8) **Material &Methods :-**
9) **Risks involved :-**
10) **Expected Results :-**

PART III

DETAILS OF THE RESEARCH PROJECT/ DISSERTATION

1. **TITLE OF THE PROJECT** :
2. **AIMS AND OBJECTIVES** :
3. **MATERIAL &METHODS :**
4. **DETAILED RESEARCH PLAN** :
5. **SELECTION OF CASES** :
6. **RISK FACTORS** :
7. **STUDY PROTOCOL :**
8. **PARAMETERS :**
9. **STATISTICAL ANALYSIS:**
10. **FACILITIES** :
11. **REQUIREMENTS :**

    Animals :

    Drugs :

    Instruments :

12. **REFERENCES :**

NAME AND SIGNATURE OF POSTGRADUATE STUDENT

(Dr……..) :

NAME AND SIGNATURE OF POSTGRADUATE GUIDE

(Dr……..) :

PROFESSOR AND HEAD,

DEPARTMENT OF…….

Velammal Medical College Hospital and Research Institute, Madurai.

Appendix 4a

INFORMED CONSENT FORM

1. I, Mr/Mrs. _____, age _____ years residing at _____ hereby give my **informed consent to participate in the** _____ _____ _____ project.

2. There is no compulsion on me to participate in this project and I am giving my free consent for it.

3. I am ready and willing to undergo all tests and treatments in the present project.

4. I have read and I have been explained the general information and purpose of the present project.

5. I have been informed / I have read the probable complications while participating in the present project.

6. I know that I can withdraw from the present project at any time.

7. Any data or analysis of this project will be purely used for scientific purpose and my name will be kept confidential except when required for any legal purpose.

8. I can read English / I can understand data read out to me in English.

Signature of the Volunteer

Signature of parent/Guardian in case of minor person.

Witnesses:

1.

2.

Signatureof thePrincipal Investigator

Prof. T. THIRUNAVUKKARASU, M.D.,D.A.,
Dean
Velammal Medical College Hospital
and Research Institute
"Velammal Village"
Madurai-Tuticorin Ring Road
Anuppanadi, Madurai-625 009. T.N.