ALL INDIA INSTITUTE OF MEDICAL SCIENCES, MADURAI

(An Institute of National Importance under PMSSY Division, Ministry of Health and Family Welfare, Government of India)

Standard Operating Procedure

(SOP)

For

Institutional Ethics Committee

(IEC)

(VERSION 1, NOVEMBER 2023)

This SOP has been prepared based on National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR 2017 the guidelines of ICMR for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki, and Good Clinical Practice ICH-GCP guidelines and New Drugs and Clinical Trial rules, 2019.

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Approved by	Dr. M. Hanumantha Rao Executive Director & CEO, AIIMS Madurai.

सत्यमेव जयते

आखिलभारतीयआयुर्विज्ञानसंस्थान,मदुरै
All India Institute of Medical Sciences
Madurai (Tamil Nadu)

Under PMSSY Division, Ministry of Health & Family Welfare, Government of India
JIPMER, Puducherry - Mentor Institute

F.NO: AIIMS-MDU/ADMN-COMT/2023/05 Dt:14.07.2023

OFFICE ORDER

Sub: Constitution of institute Ethics Committee, AIIMS Madurai- reg

Ref: National ethical guidelines for Biomedical and Health Research involving human participants- ICMR-2017

I am directed to convey that the Institute Ethics committee is constituted with the following members.

S.No	Name	Designation	Status in EC
1.	Dr. Senthil Kumar G,	Dean, Professor & Head, Dept. of Cardiology, GRMC	Chairperson/Vice Chairperson (Optional)
2.	Dr. V. Mangayarkarasi. V.	Faculty In charge (Academics), Professor & Head, Dept. of Microbiology, AIIMS, Madurai	Member Secretary/ Alternate Member Secretary (Optional)
3.	Dr. Senthil Kumaran M	Associate Professor, Dept. of Forensic Medicine and Toxicology,	Basic Medical Scientist
4.	Dr. Lena Charlette S	Assistant Professor, Dept of Community and Family Medicine,	Basic Medical Scientist
5.	Dr. Muthu Chidambaram N M.B.B.S., M. D.	Associate Professor, Dept. of Pediatrics	Clinician
6.	Mr. Ravichandra Ramavanni	Advocate, Ramanathapuram.	Legal Expert
7.	Ms. Bimla Chandrasekaran	Secretary, EKTA Resource Centre for Women, Madurai.	Social Scientist/ Philosopher/ ethicist/theologian
8.	Mr. Periyasamy	Teacher	Lay person

They shall perform functions assigned along with their regular duties. They will not be entitled for any additional remuneration in this regard.

5.9.2023

Executive Director &CEO, AIIMS Madurai.

To
The Members concerned.

Copy for information to:
DDA AIIMS Madurai.
AO, AIIMS Madurai.
Academic Section.
Guard File.

प्रो (डॉ) एम हनुमंत राव
Prof (Dr.) M HANUMANTHA RAO
कार्यकारी निदेशक / Executive Director
अखिल भारतीय आयुर्विज्ञान संस्थान, मदुरै
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GRMC, Ramanathapuram - 623503
Ministry of Health and Family Welfare
Government of India

CONTENTS

1. ABBREVIATIONS USED IN THIS BOOKLET

AE- Adverse Events

AIIMS MADURAI-AIIMS Madurai

CD- Compact Disc

CDSCO- Central Drug Standards Control Organization

CME- Continuing Medical Education

CP- Chairperson

CV- Curriculum Vieta

DGHS- Director General of Health Services

DO- Dean Office

EM- External Member

HOI- Head of the Institute

ICH-GCP- International Conference on Harmonization- Good Clinical Practice

ICMR- Indian Council for Medical Research

IEC- Institute Ethics Committee

IM- Internal Member

IRC- Institute Research Committee

LAR- Legally Authorized Representative

MS- Member Secretary

NGO- Non-Governmental Organization

OS- Office Secretary

PG- post-graduate

PhD- Doctor of Philosophy

PI- Principal Investigator

PPT- Power point Presentation

SAE- Serious Adverse Events

SOP- Standard Operating Procedure

STS- Short Term Students project

2. INTRODUCTION

Research in medical science is the scientific way of studying health and disease, collecting data/information, documenting and critically analyzing this data/information to establish facts and to reach new conclusions in accordance with appropriate methodologies specified by standard academic and professional bodies. Pivotal to any research is supervision and regulation of the whole process by qualified professionals to maintain the highest possible standards. To achieve this, our Institute has evolved the following guidelines, to be called "Standard Operating Procedure" (SOP), for members of IEC as well as researchers to strictly adhere to the principles outlined in it. The IEC will ensure that all the essential principles of research ethics viz, autonomy, beneficence, non–maleficence and justice are taken care of in planning, conduct and reporting of a proposed study. As IEC is responsible for protecting the rights and welfare of the participants as well as guiding the researchers do to research in ethical way, the SOP for IEC is a very essential document in any Institute that is involved in research. This booklet will help researchers to design their protocol in scientific manner and members of IEC to adopt scientific approach when reviewing the protocols for ethical issues.

3. AIM

To review the research proposals involving human subjects to ensure that their rights are protected according to international, national, and local guidelines as well as to monitor the progress of the study till the end so that human rights are not violated at any point of time during research.

4. OBJECTIVES

The 10 points of Nuremberg Code forms our objectives of IEC SOP.

1. The voluntary consent of the human subject is absolutely essential.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state were continuation of the

experiment seems to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required by him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

5. Membership requirement of IEC

Composition of an IEC

- IEC should be multi-disciplinary and multi-sectoral.
- There should be adequate representation of age and gender.
- Preferably 50% of the members should be non-affiliated or from outside the institution.
- The number of members in an EC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.
- The IEC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

The composition, affiliations, qualifications, member specific roles and responsibilities are:

S. No	Members of IEC	Definition/description
1.	**Chairperson/** **Vice Chairperson** (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an IEC	• 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 both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an 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 COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, IEC members, conflict of interest issues and requests for use of IEC data, etc.

2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications - • Should be a staff member of the institution • 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	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule IEC meetings, prepare the agenda and minutes • Organize IEC documentation, communication and archiving • Ensure training of IEC secretariat and IEC members • Ensure SOPs are updated as and when required • Ensure adherence of IEC 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 IEC 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 Scientist(s)** Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• 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.	**Clinician(s)** Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• 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/s** Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD 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 Qualifications - 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	• 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.	**Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health- related career in the last 5 years • May be a representative of the community from which the 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.	• 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.

Quorum requirements for IEC meetings

1. A minimum of five members presents in the meeting room.
2. The quorum should include both medical, non-medical or 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.
7. To maintain independence, the head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.
8. The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.
9. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members

and can attend meetings in the absence of regular members.

10. The IEC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.

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

12. As far as possible a separate scientific committee should priorly also review proposal before it is referred to IEC. IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

6. PROCEDURE FOR NOMINATING IEC MEMBERS - TERMS OF REFERENCES

RESPONSIBILITY: HOI is responsible to implement this SOP.

1. The Head of the Institute (HOI)/ Executive Director (ED) is responsible for selecting and nominating the Chairperson and Member Secretary of IEC.
2. The HOI, in consultation with the CP, is responsible for selecting and nominating other members (should possess adequate academic and research experience to scrutinize the proposals in terms of scientific, medical, and ethical concern) of the IEC.
3. After selection, The HOI will send official invitation to Members of the IEC to join.
4. Willing Members will confirm their acceptance by sending required documents along with their acceptance letter to the HOI.
5. The HOI will send appointment orders to the eligible Members.
6. Members have to sign the declaration and confidentiality agreement.

7. CONDITIONS OF APPOINTMENT, TENURE AND THE QUORUM REQUIRED

Conditions of Appointment

i. A member should be willing to reveal his / her full name, profession, and affiliation; all reimbursement for work and expenses, if any, within or related to the Committee as these details will be made available to the appropriate authority upon request.

ii. A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

iii. Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences.

Appointment of New Members

New members will be appointed under the following circumstances:

i. When a regular member completes his / her tenure.

ii. If a regular member resigns or drops out before the tenure is completed.

iii. If volume of proposals and frequency of review demands appointment of new members.

When a new member shall be appointed, it is advisable to induct a member in the same category to fulfil the norms the same category.

Tenure of Membership

i. The tenure of Committee Membership will be a continuous period of 3 (three) years.

ii. Extension of membership will be decided by Head of Institute.

iii. There will be limit to the number of times that membership can be extended. To avoid Conflict of Interest (COI) and to bring new ideas and dimensions in the review, limitation the extension should be up to 1 or 2 times.

Quorum of Committee

The regular member of the committee will ideally include at least 7 and maximum of 15 individuals as follows:

i. Chairperson: 1
ii. Member Secretary: 1
iii. Basic Medical Scientist: 1-2
iv. Clinicians: 1-2
v. Legal Expert: 1-2
vi. Social Scientist / Social Worker / Ethicist: 1-2
vii. Lay Person preferentially a non-professional lady from the community: 1-2

a. The Committee will have representation from both men and women.

b. All members will act in the manner independent of any influence of the existing relationship with any organization, institute or individual.

8. PROCEDURE OF RESIGNATION REPLACEMENT AND REMOVAL OF MEMBERS

The membership will stand to be terminated under the following circumstances:

i. If a member resigns from the Committee
ii. If a member is incapable of performing his / her duty as a committee member.
iii. In case of demise of a member.
iv. Rotation system for membership will be considered to allow for continuity, development, and maintenance of expertise within the Committee and regular input of fresh ideas and approaches.
v. In case of resignation,

Any member may resign before completing their terms by writing their intention to the Chairperson. The members have to serve for 1 (one) month notice period before they can be relieved. However, the Chairperson shall review the same and decide whether to allow the member to leave the Committee with immediate effect or after serving the notice period of 1 (one) month.

Honorarium to the members

The reimbursement of travelling expenses and/or reasonable honorarium for attending IECwill be given only to external IEC members.

9. THE TERMS OF REFFERENCE OF THE COMMITTEE / RESPONSIBILITITES

- The head of the institution should appoint all IEC members, including the Chairperson.

- The appointment letter issued to all members should specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following:
    - Role and responsibility of the member in the committee
    - Duration of appointment
    - Conditions of appointment

- Generally, the term of IEC membership may be 2–3 years. The duration could be extended as specified in the SOPs. A defined percentage of IEC members could be changed on a regular basis.

- IEC members may be given a reasonable honorarium for attendance at the meeting.

- Members to be appointed on the IEC should be willing to fulfil the IEC requirements.

Roles and responsibilities of the IEC

- The basic responsibility of an IEC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

- The IEC must ensure ethical conduct of research by the investigator team.

- The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

- The IEC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

- The IEC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

- The IEC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

- Responsibilities of members should be clearly defined. The SOPs should be given to IEC members at the time of their appointment.

- The Chairperson should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

- The IEC should ensure that privacy of the individual and confidentiality of data including the documents of IEC meetings is protected.

- The IEC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

- The IEC should recommend appropriate compensation for research related injury, wherever required.

- The IEC should carry out monitoring visits at study sites as and when needed.

- The IEC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

- The IEC may see that conduct of same/similar research by different investigators from same institution is harmonized. ‘Me too’ research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

10. TRAINING OF EXISTING AND NEW MEMBERS

1. The members should update their knowledge on ethics by attending various national and international conferences on ethics yearly once.
2. All members must get familiarized with the guidelines of ICMR for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki, and Good Clinical Practice ICH-GCP guidelines.
3. The members should update their knowledge on Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017 and New Drugs and Clinical Trial rules, 2019

11. Conflict of interest

Conflict of interest (COI) is a condition where a primary interest such as participants welfare or the validity of research takes a back seat and secondary interest like financial or non-financial (personal, academic or political) takes center stage. COI can be at the level of institutions, researchers, or IEC members.

Research institutions must:

- Develop policies and SOPs to address COI issues.
- Policies and procedures to identify conflicts of interest and educate staff about such conflicts.
- Monitor the research for accuracy and objectivity
- Do not interfere in the functioning and decision making of the EC.

Researchers must:

- Researchers are advised and ensure that the documents submitted to the EC include a disclosure of interests that may affect the research.
- Prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students.

IECs must:

- IECs must evaluate all studies submitted.
- Appropriate suggestions if COI is detected at the institutional or researcher's level.
- All IEC members to disclose their own COI (Confidentiality Agreement form to be filled & signed) and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI.
- COI within the EC should be declared and managed in accordance with standard operating procedures (SOPs) of that EC (Undertaking regarding COI form to be filled & signed).

Conduct of Meeting: The members should gather in IEC meeting room on scheduled time. If an IEC member has conflict of interest involving a project, then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes.

Decision Making Process: IEC member will withdraw from the meeting for the decision procedure concerning the study where conflict of interest exists. If any IEC member has her/his own proposal for IEC

review he/she will not participate in the IEC discussion or vote on that particular project. Decisions will only be made at meetings where a quorum is present. Neither PI nor any of proposed study team members participated during the decision making of the IEC. Only IEC members who attend the meeting will participate in the decision.

12. TYPES OF RESEARCH

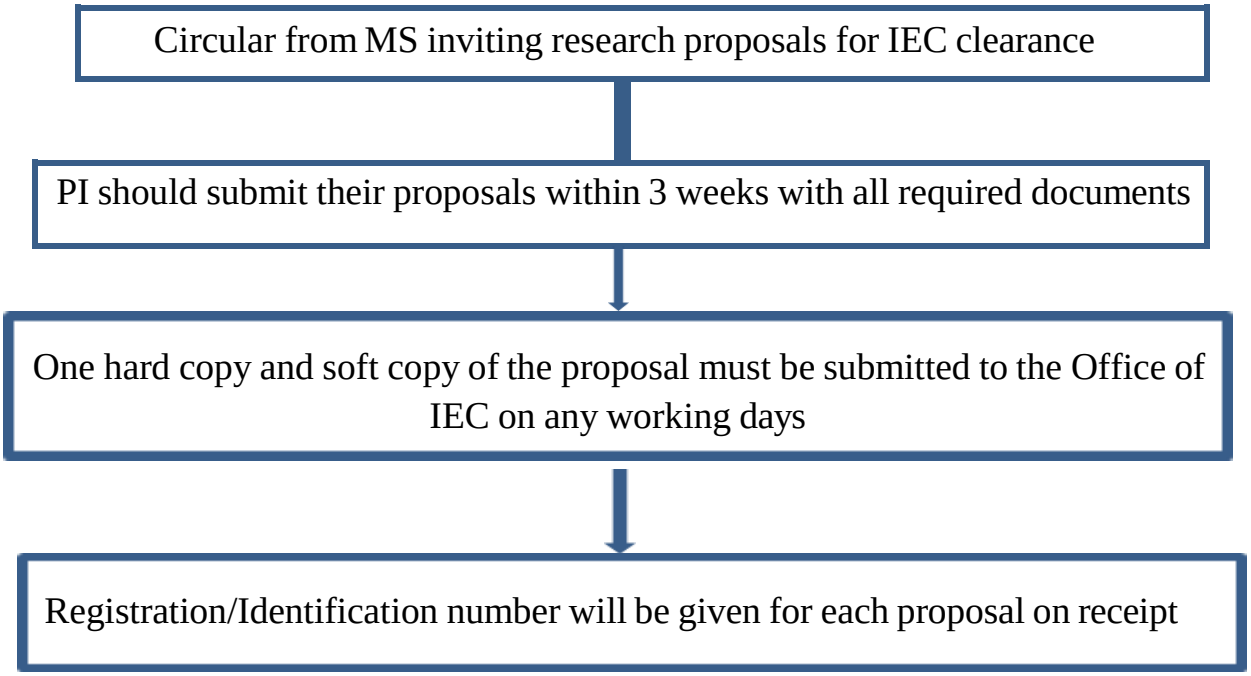
- Clinical Research
- Clinical trial Drug and Vaccine
- Diagnostic trial
- Observational studies
- Clinical pharmacology research
- Epidemiological studies
- Observational studies
- Operational research
- Laboratory research
- Socio-behavioural research
- Observational studies
- Interventional studies

13. PROCEDURE FOR SUBMISSION OF RESEARCH

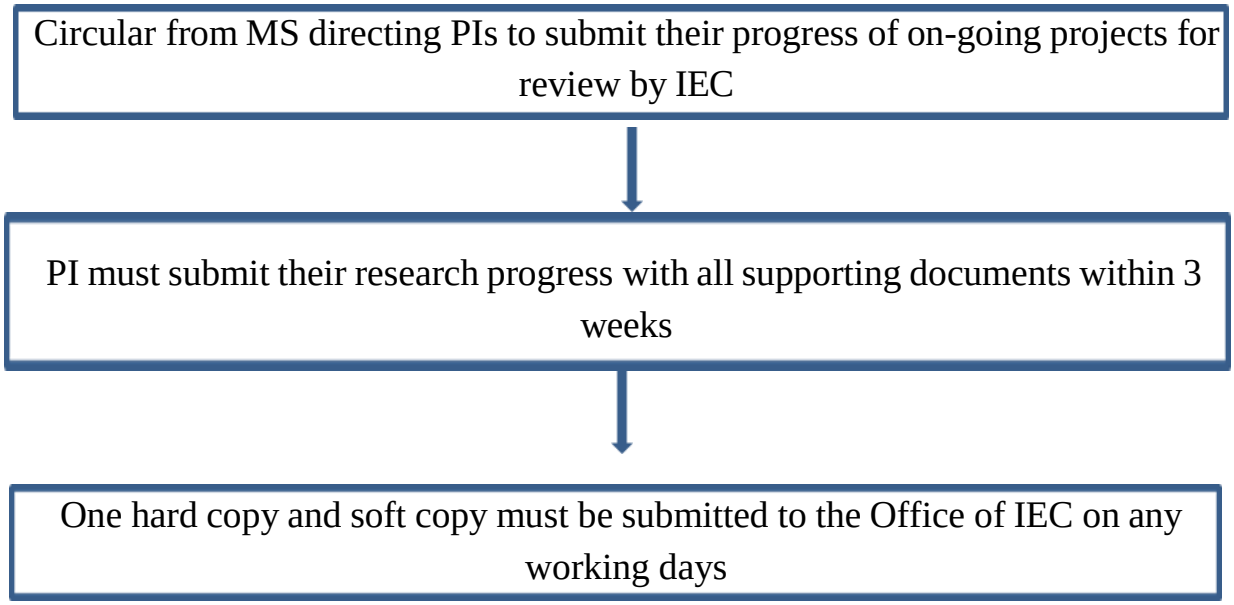
RESPONSIBILITY: PIs of the research proposals.

PROCEDURE:

1. For fresh research proposals:



2. For on-going projects:



14. INITIAL SCRUTINY OF SUBMITTED PROPOSALS

RESPONSIBILITY: The office secretary and MS of IEC.

PROCEDURE:

The proposals that have cleared IRC scrutiny only will be taken for IEC review process

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The OS will check for the completeness of the submitted proposals

↓

If the proposal is incomplete, the PI is informed about it by the MS

↓

The PI must correct the proposal according to the recommendation and resubmit the proposal.

↓

The MS will check whether the suggestions by the IRC were adequately addressed by the PI

↓

The OS will compile all the completed proposals, department wise for presentation at IEC meeting.

15. PROCEDURE TO REVIEW THE SUBMITTED RESEARCH PROPOSALS

RESPONSIBILITY: All the members of IEC are responsible to carry out this procedure.

PROCEDURE:

The proposals would reach each IEC members at least 2 weeks before intended IEC meeting.

↓

Each IEC members should scrutinize the proposals on ethical issues, scientific approach and technical appropriateness using the checklist.

↓

The PI should present his research proposal in PPT in the presence of all IEC members during the notified meeting.

↓

The IEC members should bring to the notice of PI, whatever inadequacies they have noted beforehand using the checklist.

↓

The PI must provide convincing and appropriate answers to the doubts raised by the IEC members.

↓

External subject expert may be asked to give expert opinion, if needed.

↓

Decision will be taken for each proposal, at the end of the meeting, taking adequate time for discussion for each proposal.

16. REVIEW OF PROTOCOL DEVIATION / VIOLATION / NON-COMPLIANCE

Purpose:

- To give right directions to the investigators(s), whenever there is Protocol Deviation / Violation / Non-Compliance to the approved protocol by the IEC.
- To strictly adhere to the national, international regulations/guidelines related to the Protocol Deviation / Violation / Non-Compliance from time to time.
- To provide adequate explanation for the Protocol Deviation / Violation / Non-Compliance to the IEC in context to ethical, scientific, statutory, or administrative matters

Scope:

- This SOP is applicable to all the research protocols (pertinent to human related research or their any biological samples or secondary data) approved by the IEC.

Responsibility:

- The IEC office will receive all the Protocol Deviation / Violation / Non-Compliance related matters in the prescribed format by the investigator(s)
- These matters will be included in the agenda of the IEC meeting for detailed explanation and further discussion.
- The IEC members will review such reports and take appropriate action.

Definition: Protocol Deviation/Violation / Non-Compliance:

Any deviation/change in the protocol from the approved latest version of the protocol by the IEC. Some of the examples include:

- Enrolment of study participant(s) who is not meeting the inclusion or exclusion criteria as mentioned in the approved latest version of the protocol by the IEC.
- Study participant(s) received a wrong drug/inappropriate dose/improper regimen etc. when compared to the approved latest version of the protocol by the IEC.
- Any wrong methodology/procedure(s) adopted in the study other than what has been mentioned in the approved latest version of the protocol by the IEC

- Use of any documents/parameters including ICD or questionnaire or CRF other than what has been mentioned in the approved latest version of the protocol by the IEC

Detection of Protocol deviation/ non-compliance/ violation:

The IEC members or designated members from the DSMB who are closely monitoring the research including its site can detect the Protocol deviation/ non-compliance/ violation, when the research project is not conducted as per the approved latest version of the protocol by the IEC. It can also be detected while reviewing the annual/periodic reports or SAE reports; It is also taken into consideration, when somebody raises the issue of Protocol deviation/ non-compliance/ violation which can be from the sponsor/funding agency/CRO/ study site/any other sources.

Procedure for Reporting Protocol deviation/ non-compliance/ violation:

- The PI will respond by reporting the Protocol deviation/ non-compliance/ violation in the prescribed format to the IEC office in stipulated time.
- This matter will be put up in the agenda by the Member Secretary for further elaboration and discussion in the full board IEC meeting.
- The proceedings in the IEC meeting will be recorded in the minutes of meeting and finally communicated to the concerned PI.

Procedures for Handling Suspected Noncompliance:

- The Member Secretary (MS) will receive any suspected Protocol deviation/ non-compliance/ violation and will confirm the authentication for the same in consultation with the chairperson of IEC.
- After this MS in consultation with chairperson will put up this matter in the agenda in the full board IEC meeting
- Further the issue will be discussed in the IEC meeting by all the members within a week after the receipt of allegation.
- In the meeting various records/sources pertaining to the Protocol deviation/ non-compliance/ violation will be checked further in detail with the research team. Study participants, or any other sources which is found to be relevant to the matter.

- The seriousness of Protocol deviation/ non-compliance/ violation is decided by the IEC members like non-serious and non-continuing or serious or continuing noncompliance that warrants investigation by the IEC or has no basis in fact and the summary of discussion in the IEC meeting will be recorded in the minutes.
- Depending upon the seriousness of Protocol deviation/ non-compliance/ violation, the IEC may take decision to immediately terminate/stop the ongoing research project.
- Wherever applicable, this issue will be communicated to the competent higher authorities including the concerned national regulatory bodies or funding agencies for further necessary actions.

17. PROCEDURE TO REVIEW PROPOSALS INVOLVING VULNERABLE SUBJECTS

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so. These vulnerable persons have some common characteristics which are listed.

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited.
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled.
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions.
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Principles of research among vulnerable populations

- Vulnerable populations have an equal right to be included in research so that benefits occruing from the research apply to them as well.
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
- Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

Stakeholders	Obligations / duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.
Ethics Committees	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • IECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in • place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research • team if the research is on sensitive topics.

18. PROCEDURE FOR DECISION MAKING

RESPONSIBILITY: All members of IEC.

PROCEDURE:

QUORUM REQUIRED:

Decision will be taken only when the quorum has at least 50% of its original strength, with the following members representing it.

1. Basic medical scientist (preferably a pharmacologist).
2. Clinician.
3. Lawyer.
4. NGO person and
5. A layman.

Any member having conflict of interest must inform it to the Chairperson prior to the meeting and it must be recorded in the minutes of meeting by the MS.

Members with conflict of interest must not take part in the decision making process.

Adequate time must be given for discussion of each proposal in the absence of its PI.

Only members who have participated in the discussion during presentation by the PI are eligible to contribute in decision making process.

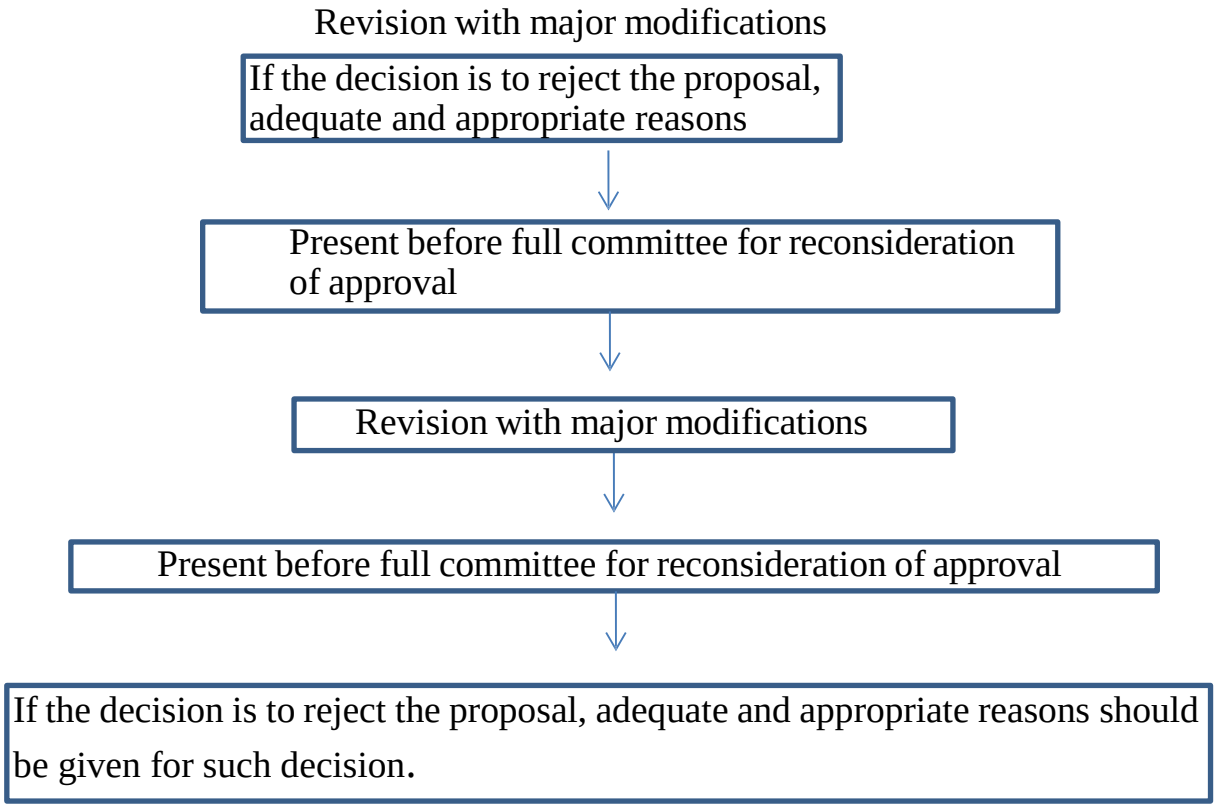
Consensus of members is essential for making a decision, but when consensus is impossible, decision can be arrived by resorting to voting.

Decision given may be simple and straightforward or with condition, if any, with appropriate recommendations and re-review procedure.

The decision may be,

1. Approved with or without comments/suggestions,
2. Revision with minor amendments,
3. Revision with major modifications and
4. Rejected

Course of proposal when the decision is “Revision”



19. PROCEDURE FOR COMMUNICATING THE COMMENTS OF IEC TO THE PI

RESPONSIBILITY: MS.

PROCEDURE:

1. The progress of all studies, which has received a positive decision, will be reviewed by IEC from the time of decision till the completion of the research.

2. The Progress of all the research proposals will be followed at regular intervals (at least once a year). Based on the need of the study, IEC may conduct the follow up review at shorter intervals.

3. All the requirements and procedures for follow up review will be similar to that of initial and main review.

4. The comments of the IEC will be communicated to the PI in writing, within 10 days of the meeting.

5. The communication of the comments will include:

a) Name and address of IEC.

b) The date and place of decision.

c) The name and designation of the applicant.

d) Title of the research proposal reviewed.

e) The registration number of the project.

f) Comments about the progress of the study/adequacy of documentation/maintenance of data sheets.

g) Signature of the Chairperson and Member Secretary with date.

20. PROCEDURE FOR COMMUNICATING THE DECISION OF IEC TO THEPI.

RESPONSIBILITY: MS is responsible for implementing this SOP.

PROCEDURE:

1. A decision of the IEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format.

2. If a proposal is approved, the IEC will issue an approval certificate signed by the CP and MS. The applicants can get the same from the office of the MS, within one week of intimation, after duly signing in the prescribed form.

3. All the approvals will be valid for only three years or for the duration of the project whichever is less.

4. The PI has to get his or her project re-approved after three years if necessary.

5. The communication of the decision will include:

a) Name and address of IEC.

b) The date and place of decision.

c) The name and designation of the applicant.

d) Title of the research proposal reviewed.

e) The clear identification of protocol number

f) A clear statement of the decision reached.

g) Any advice by the IEC to the applicant.

h) In case of conditional approval, statements/suggestions regarding the changes to be made.

i) In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

j) Signature of the MS with date.

21. CONDUCTING IEC MEETINGS

RESPONSIBILITY: The CP and MS are responsible for fulfilment of this SOP.

PROCEDURE

1. The MS in consultation with the CP will convene IEC meeting every 3 or 4 months. If the number of proposals is more, additional IEC meetings can also be arranged.

2. All the proposals should reach the MS at least 3 weeks before the scheduled meeting.

3. The received proposals will be checked for its eligibility for presentation, first by the OS followed by the MS.

4. The proposals which have cleared the IRC review only will be taken up for IEC review.

5. The proposals that have fulfilled the eligibility for presentation will be sent to the Members of the IEC for further scrutiny, at least 10 days before the meeting.

6. The PI along with their Guide/Co-Guide will be asked to make a PPT presentation of their proposal during the IEC review meeting.

7. External subject expert may be called to give their opinion if a proposal needs so. But they are not eligible in the decision-making process for a proposal.

8. The deliberation and decision of the meeting has to be meticulously noted in the Minutes of the meeting by the MS and the same should be circulated to all the Members ofthe IEC, after CP and MS sign the Minutes of meeting.

9. IEC meetings should take place at regular intervals and at specified dates.

10. Tentative IEC meeting will be conducted every three months, and this will be changed to monthly meetings depending upon the project received for approval.

11. The PI must submit the progress of the study, annually, in the prescribed format to the IEC.

12. The final report of the completed study must be submitted in the prescribed format to the IEC by the PI.

22. DECISION MAKING PROCESS ON PRESENTED PROPOSALS

RESPONSIBILITY: All members of IEC are responsible for this process.

At least 50% of the total strength of IEC should be present which should include one basic medical scientist, one clinician, one legal expert, one NGO representative and one lay person. (One of the members should be an external

Only application that has passed the initial perusal (complete in all its aspects)will be considered for this process

Adequate time must be given for each proposal, so that all aspects are given due importance.

Decision must be taken in the absence of PI or other members involved in the project

The members who have participated in the review and discussion only should participate in decision making

Decision should be taken on consensus of all members. If not, it should be taken after voting

23. RECORD KEEPING AND ARCHIVING:

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.

2. Only who are authorized by the CP of IEC will have the access to the various documents.

3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.

4. No document (except agenda) will be retained by any IEC member.

5. At the end of each meeting, every member must return the CD containing all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

6. Following documents will be filed and archived with proper label on the top of file for easy identification.

a. Constitution and composition of IEC, AIIMS, Madurai

b. Curriculum Vitae (CV) of all members of IEC, with records of training in Human ethics if any.

c. Standard Operating Procedures of IEC, AIIMS, Madurai

d. Annual reports

e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members.

f. The published guidelines for submission established by the EC.

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

h. Agendas and Minutes of all IEC meetings duly signed by the CP / MS.

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

j. Copy of all correspondence with members, PI and other regulatory bodies.

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

l. Final report of the approved projects, including microfilms, CDs and Video recordings.

24. LETTER FOR INVITING PERSONS TO BE CP/MEMBER OF IEC

No. AIIMS MADURAI/DO/IEC/20 Date:

From,

The Executive Director,

AIIMS, Madurai,

Tamil Nadu.

To,

_____

_____

_____

Sub: consent to be Chairperson/ IEC member – Reg.

Dear sir/madam,

We are in the process of constituting/revamping our IEC for AIIMS, Madurai. To keep up the high standards, I hereby request you to declare your willingness to be Chairperson/member of our IEC. Kindly send your acceptance in the given prescribed format.An official appointment letter will be sent to you upon receipt of your acceptance letter.

Yours sincerely,

25. LETTER FOR WILLINGNESS TO BE CP/MEMBER OF IEC

No. AIIMS MADURAI/DO/IEC/20 Date:

From,

_____

_____

To,

The Executive Director,

AIIMS, Madurai,

Tamil Nadu.

Sub: Consent to Chairperson/IEC member – Reg.

Dear sir/madam,

This in response to your letter stated above, I affirm my willingness to be the Chairperson/member of IEC, AIIMS, Madurai.

I will carry out the responsibility entrusted upon me to maintain the high standards of IEC, AIIMS, Madurai.

Please find my updated CV along with this letter.

Yours sincerely,

_____

26. CV OF MEMBERS OF IEC

Name:

Age: Sex:

Designation:

Institution:

Cell: e-mail:

Educational qualifications:

Sl.no	Degree/Diploma/Certificate	Year	Institute/University

Experience in other academic committees:

Sl.no	Post/Position held	Year	Institute/University

Signature

Place: Date:

No. AIIMS MADURAI/DO/IEC/20 Date:

27. SECRECY UNDERTAKING BY MEMBERS OF IEC

Name:

Designation:

Institute:

As a member of IEC, I may receive important documents that contain confidential information about patient, drug, procedure or equipment. I will not disclose this information to any person who is not involved in IEC. I also promise that the documents related to the research will be returned to the MS after IEC meeting.

Signature

Place: Date:

No. AIIMS MADURAI/DO/IEC/20 Date:

28. OFFICE ORDER

The following dignitaries are appointed as members of IEC, AIIMS, Madurai. The tenure of this team is for 3 years from the date of appointment.

1. _____ Chairperson
2. _____ Co-Chairperson
3. _____ Member Secretary
4. _____ Basic medical scientist
5. _____ Basic medical scientist
6. _____ Basic medical scientist
7. _____ Clinician
8. _____ Clinician
9. _____ Clinician
10. _____ Ethicist
11. _____ Social Scientist
12. _____ NGO representative
13. _____ Legal expert
14. _____ Lay person

Executive Director,
AIIMS, Madurai, Tamil Nadu.

29. INSTITUTIONAL ETHICAL COMMITTEE APPROVAL LETTER

Government of India

Ministry of Health and Family Welfare

PMSSY

All India Institute of Medical Sciences

Madurai, Tamil Nadu

Ethics Clearence No. AIIMS/MADURAI/IEC/ 2023/ Date:

This is to certify that research proposal titled _____

_____

_____done by Dr/Mr./Ms._____ of _____ Department guided by_____has been approved by the IEC, AIIMS, Madurai, at its meeting held on_____at_____am/p.m. The IEC, AIIMS, Madurai approved the project and the project will be reviewed periodically. The validity of this approval is for 3 years or the duration of the study, whichever is less.

Member Secretary,
IEC, AIIMS, Madurai,
Tamil Nadu.

Chairperson,
IEC, AIIMS, Madurai,
Tamil Nadu.

30. CONSENT FORM **PART 1**

PATIENT/PARTICIPANT INFORMATION SHEET

This information sheet should contain all relevant information in simple non-technical terms, easily understandable by a lay person, regarding your study. The information must be provided under the following headings and sequences.

1. Title of the study.

Participating subject should able to understand your heading/title of the study.

2. Invitation to take part in the study.

Before going into the details of the study, express in few lines regarding their freedom in participating in the study. An example is given below;

"We welcome you to take part in the study. You have all the rights to decide to take part or not to take part in the study. This document contains all relevant information regarding this study. It also mentions benefits, discomfort or possible risks involved in this study. We help you in the process of decision making by providing all relevant information regarding this study. Therefore, take adequate time to read what is given in this sheet and you are free to discuss about this with your friends, colleagues, family members or your treating physicians. We are also ready to clarify any doubts in your minds regarding this study".

3. What is the purpose of the study?

State the aim of the study in simple terms.

4. Why I have been chosen?

List out the criteria used to select the subjects for this particular study.

5. Do I have to take part?

Tell that taking part in the study is entirely their voluntary decision. It can be stated as follows;

"Decision to or not to take part in the study is entirely your own choice. If you choose to be part of the study, then a copy of this sheet will be given to you for your reference and you need to sign a consent form. Even after agreeing to take part in the study, you can withdraw from the study at any point of time, without giving any reason for your decision. Doing so will not affect the standard of treatment/care you receive."

6. What will happen to me if I take part?

Explain them that they will be called for basic physical examination / to fill up questionnaire form/ intervention/ newer treatment/ follow up. State how often and how long they need to come. Assure them that no injury will be inflicted on them.

7. What do I have to do?

Tell them whether they need to follow certain type of life style (life style modification), change in their routine daily activities, can they continue to take their regular medication.

8. What is the drug or procedure that is being tested?

Give full information regarding the drug viz., type, dosage, route and frequency of administration, possible side effects, before or after food. Same way gives complete information on procedure viz., name, invasive or non-invasive, involves withdrawal of blood or not, possible side effects and safety measures.

9. What are the alternatives to the diagnosis or treatment?

They should be made known about availability of alternatives to the proposed diagnosis or treatment. That gives them the freedom to decide to join the research or refrain from it.

10. What are the side effects of taking part in the study?

List all the possible side effects of the drug or procedure in simple terms without using medical jargons so that the subject understands what is written. For example, instead of using terms like anemia or polycythemia, use simple terms like decreased or increased red blood cells. Some side effects may be unknown or new for that particular drug or procedure. Therefore, advise them to contact you or any other persons involved in the research in case they notice the known side effects or some unusual manifestations. For this they must have yours as well as other investigators address with contact number.

11. What are the possible disadvantages or risks of taking part in the study?

Pregnancy poses a possible disadvantage or risk in taking part in any study. So, give clearwarning as follows:

“The drug or the procedure may affect your unborn baby. Therefore, do not take part in thisstudy if you are pregnant or planning to become pregnant during the course of the study. Incase if you become pregnant during the study period, intimate this to the PI or other Investigators, who will relieve you from the study.”

Do screening of women subjects for pregnancy before the start of the study. Advise them to use effective contraceptive methods if they are in the reproductive age group.

Same concern should be given to male subjects. The study should not affect their sperm or sexual life.

12. What are the possible benefits of taking part in the study?

The subjects should not be lured into the study by giving exaggerated information regarding the benefits of the drug or procedure. They should not also be coerced into the study by threatening them by stating exaggerated disadvantages if they do not take part in the study.

Therefore, it is advisable to state that the benefits of the drug or procedure are not known at present, but this study may benefit the treatment of future patients.

13. What if new information becomes available?

Any new information becomes available during the course of study, it will should be shared with the subject. State it as follows:

"During the course of the research, if we get any new information, it will be shared with you. Based on the new information, you can decide by yourself whether to continue the research or not. If you like to withdraw from the study, we will make all necessary arrangements to continue your medical care that have been getting from us. Withdrawing from the study will not affect the medical care given by us. If you like to continue, then you need to sign a new updated consent form."

14. What happens when research stops?

When the research stops due to some reason, exact reason must be told to the subject. If the sponsoring company stops sponsoring, the subject must be informed about other alternative drug/procedure.

15. What if something goes wrong?

The participants must know that there is a process/procedure in place to handle the complaints from them. Assure them that measures will be taken to rectify their grievances. If some serious events happen, the study must be stopped.

16. Will my taking part in the study be kept confidential?

Permission must be sought from the participants to get access to their medical records for necessary vital information. The information (of the subjects) that will be available during the course of the research should be strictly maintained confidentially. Though the data will be shared with other people, the identity of the subjects will not be revealed.

17. What will happen to the results of the research?

Inform them that the results of the research will be used for publishing the article in scientific journals and presentation at conferences.

18. Who is organizing and funding the research/trial?

Provide information whether the researcher is getting any financial aid from Govt., NGOs, pharmaceutical companies, organization or institution. If funded, state for what purpose the money being used viz., equipment, lab tests/ reagents, drug, procedure, etc.,

19. Who has reviewed the study?

Mention that IEC, AIIMS Madurai, has reviewed and approved the study. However, don't mention the individual names of the members of IEC who have reviewed and approved the study.

20. Contact for further information:

Give complete contact details about the PI to the participant.

Name of the PI:

Cell number: e-mail:

Designation:

Name of the Institute:

Place: Signature of PI

31. CONSENT FORM **PART 2**

Title of the project: _____

_____

Research project number: Participant identification number:

Name of the Principal Investigator: _____

Cell no. _____

I have read the Patients/Participants Information sheet/ the contents of the Patients/Participants Information sheet have been explained to me in detail in my own language, and I have understood it completely what is conveyed in the sheet. Members havecleared my doubts when I asked for clarifications. Members also explained to me the purpose, methods/procedure, risks involved and duration of the study. I know that my participation in this research is entirely voluntary and I have all the rights to withdraw from the study, if I decided to do so even in the middle of the study. Further I understand that withdrawing from the study will not, in any way, affect my medical care from the Institute.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

.....(Signatures / Left Thumb Impression)

Place:

Date:

Name of Participant:_____Son/Daughter/spouse of_____.

Complete postal address_____
_____
_____.

This is to certify that the above consent has been obtained in my presence.

Date: Signatures of the PI

Place:

1) Witness – 1 2) Witness – 2

---------- ----------

Signature Signature

Name: Name:

Address: Address:

NB: Three copies should be made, one each for (1) Patient, (2) Researcher and (3) Institution.

(Investigators are advised to prepare the translation in simple understandable Tamil on their own).

32. COVERING LETTER

From

Name of the Principal Investigator

Designation

Department

Institute & Place

To

Chairperson/Member Secretary

IEC

AIIMS

Madurai

Respected Sir/Madam

Sub: I am here by submitting the 'Research Proposal' with title '…….'. Kindly give me permission to carry the above research proposal.

Place: Yours sincerely

Signature of Principal Investigator

Date:

33. ENCLOSURES

Ten (10) copies of the followings are enclosed:

1. Proposed **Research Protocol**
2. **Informed Consent Document (ICD): Part 1** [Participant Information Sheet (PIS)] in English & Tamil language(s)
3. **Informed Consent Document (ICD): Part 2** [Informed Consent Form (ICF)] in English & Tamil language(s)
4. **Permission Letter** obtained from the Executive Director/HOD/Concerned HOD [*If study isinterdepartmental*] (Photocopies only)
5. **Certificate of Approval** obtained from the Institutional Research Committee (IRC) (*Photocopies only, If applicable*)
6. **Case Record Form (CRF) / Questionnaire** applicable to research proposal
7. **Single CD** containing the scanned soft copies [*In **PDF format***] of all the above.

Note: *Consent form part 1 and 2 should be translated in Tamil languages exactly as in English.*

34. SUBMISSION OF RESEARCH PROPOSAL TO INSTITUTIONAL ETHICS COMMITTEE (IEC)

PRELIMINARY DETAILS OF PRINCIPAL INVESTIGATOR/CO-INVESTGATOR(S)

1. **Principal Investigator:**
   - **i.** Name:
   - **ii.** Designation:
   - **iii.** Department:
   - **iv.** Institution Details:
   - **v.** Email ID:
   - **vi.** Contact No.:

2. **Co-Investigator:**
   - **i.** Name:
   - **ii.** Designation:
   - **iii.** Department:
   - **iv.** Institution Details:
   - **v.** Email ID:
   - **vi.** Contact No.

3. **Co-Investigator [***If two or more co-investigators***]**
   - **i.** Name:
   - **ii.** Designation:
   - **iii.** Department:
   - **iv.** Institution Details:
   - **v.** Email ID:
   - **vi.** Contact No.

4. **Updated Curriculum Vitae of Principal Investigator:**

5. **Updated Curriculum Vitae of Co-Investigator(s):**

35. RESEARCH PROTOCOL PROFORMA

6. **TITLE OF THE STUDY (Maximum 20 words):**

7. **BACKGROUND OF STUDY (Maximum 300 to 350 words):**

8. **SCIENTIFIC JUSTIFICATION OF THE STUDY:**

9. **AIMS AND OBJECTIVES**:

10. **REVIEW OF LITERATURE:**

11. **WORK ALREADY DONE (***If any pilot studies or others specify***)**:

12. **MATERIALS AND METHODS:**

    a. Study Design:

    b. Study Setting (*Exact place where the study is conducted*):

    c. Approximate Total Duration of The Study:

    d. Number of Groups to Be Studied:

    e. Detailed Description of The Groups:

    f. Sample Size of Each Group:

    g. Total Sample Size of The Study:

    h. Scientific Basis of Sample Size Used in The Study:

    i. Sampling Technique Used in The Study:

    j. Inclusion Criteria:

    k. Exclusion Criteria:

    l. Whether Placebo Used in Study (Yes/No):

    m. Whether Drugs/Medical Devices Used in The Study (Yes/No):

    n. **IF DRUGS/MEDICAL DEVICES USED:**

    i. Whether The Drug/Medical Device Used Is for **Newer Indication**:

    ii. Whether The Drug/Medical Device Used Is for **First Time in Human Beings**:

    iii. If Used for Newer Indication/First Time in Human Beings, Whether the Permission Obtained from The **Drug Controller General of India** (DCGI):

iv. **Formulation** of The Drug Used:

v. **Name** of The Drug/Medical Device Used (Non-Proprietary Name, Brand Name, Company/Manufactures Details):

vi. **Dose** of The Drug Used:

vii. **Frequency** of The Drug Used:

viii. **Route of** The Drug Used:

ix. **Duration** of The Drug Used:

x. **Steps** to be Taken to Prevent Adverse Drug Reactions **(ADRs):**

xi. In Case of Severe ADR, **Mode of Management:**

xii. In Case of Drug Related Injury, **Agreement of Compensation**:

xiii. Any Other Relevant Details:

o. **<u>If Research Proposal is a CLINICAL TRIAL</u>:**

I. Registration with Clinical Trial Registry of India [CTRI] (*Provide Details*):

II. Clinical Trial Design (Example: Open Label/Parallel/Factorial etc.):

III. Clinical Trial Done at (Single Site/Multicentric):

IV. Allocation Ratio of Different Groups:

V. Randomization (Yes/No):

VI. Type of Randomization:

VII. Method Used to Generate Random Sequence Numbers:

VIII. Allocation Concealment Mechanism:

IX. Type of Blinding Used (*If any*) [Provide in Detail]:

p. **Parameters to be Studied [**If *quantitative data mention the units of measurement (MUST)***]:**

q. **Method(s)/Technique(s)/Instrument(s)/Reagent(s)/Kit(s) etc. Used to Measure the Quantitative Parameters Along with Their Manufacturing Source Details [MUST]:**

r. **Procedure in Detail (***Explain, if Possible, with Flowchart***):**

s. **Statistical Methods of Analysis:**

   i. Significance Level Decided Before Starting of Study:

   ii. Statistical Tests to Be Used for Data Analysis:

   iii. Software(s) To Be Used for Statistical Analysis:

13. **HYPOTHESIS (***If any***):**
14. **REFERENCES (***Minimum 10 References in Vancouver Format Only***):**
15. **GIVE DETAILS OF THE FOLLOWING:**

A. Whether The Study is **Intradepartmental** or **Interdepartmental**:

B. If Interdepartmental Whether Consent

Obtained from the Department (s) Concerned:

C. If Interdepartmental Whether the Permission

Letter from The Concerned HOD Enclosed/Not:

D. Any Extra Materials / Finance Required/Obtained

to Carry Out the Study:

E. If Yes, Write in Detail About the Source of Finance:

(*Whether From Funding Agencies/Institute/Investigator (Self)/Others If Any Specify*):

36. DECLARATION BY THE INVESTIGATOR(S)

A. I certify that the research proposal here in is not necessarily the duplicate of previously reported research.

B. I will obtain approval from the Institutional Ethics Committee (IEC) of AIIMS, Madurai before starting my research proposal.

C. I will obtain the approval from IEC of AIIMS, Madurai before initiating any significant changes in the study.

D. I certify that performances of research will be carried out in accordance with the GCP & GLP guidelines laid by the international & national organizations/bodies from time to time.

E. I will maintain all the records pertaining to my research activities and will produce before to IEC for scrutiny if required.

Date:

Place:

Signature of the Principal Investigator

Name of the Principal Investigator

Designation

Department

Institute

Place with PIN code

Mobile number

Email ID

Along with Seal

Signature of Co-Investigator	*Signature of Co-Investigator*	*Signature of Co-Investigator(s) (if > 2)*
Name of the Guide	Name of the Co-guide	Name of the Co-guide
Designation	Designation	Designation
Department	Department	Department
Institute	Institute	Institute
Place with PIN code	Place with PIN code	Place with PIN code
Mobile number	Mobile number	Mobile number
Email ID	Email ID	Email ID
Along with Seal	Along with Seal	Along with Seal

37. UNDERTAKING BY THE INVESTIGATORS

1. Full name, address, and title of the 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 will be 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 subject, 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 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.
xi. I will maintain confidentiality of the identification of all participating subjects 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 trials.

8. Signature of Investigator with date.
9.

Sl. No.	INVESTIGATORS	DESIGNATION	SIGNATURE
		PI	
		Co-Investigator	
		Co-Investigator	
		Guide	
		Co-Guide	
		Co-Guide	

38. Guidelines/ Check list for Research Protocol Submission to IEC, AIIMS, Madurai

Sl. No.	ITEMS
1	Submission to Dean/ Faculty In-charge research and final approval/permission letter from the competent authority, Head of the Institution (Executive Director, AIIMS, Madurai)
2	Approval/Permission letter from the competent authority of District/Regional/State/Nation/Other Govt. Offices/Departments/Regulatory agencies (Wherever Applicable)
3	Approval/Permission letter from the other committee(s) as per the existing National/International Regulations & Guidelines (Wherever Applicable)
4	Approval/Permission from the respective Head of Department(s)/HODs concerned [In Intradepartmental/Interdepartmental Research Proposal(s)]
5	Approval/Permission from the 'Copyright Owners' if any scientific method(s) is used in the research protocol [Wherever Applicable]
6	'Good Clinical Practice (GCP) Training Certificates' for Principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s) [In the last 3 years of period]
7	Declaration of 'Total Number of Research Projects' currently handled by the principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s) including their details
8	Adherence of research protocol in the format provided by the IEC, AIIMS, Madurai
9	Declaration of 'Conflicts of Interest' by the Investigator(s) (If involved in the research)
10	Covering letter with date and signature of Principal Investigator (PI)
11	Updated 'Curriculum Vitae' of Principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s)
12	Adequate scientific justification of the study with adequate references
13	Adequate review of literature pertinent to the current research protocol
14	In detailed description of 'Methodology' of the Research Protocol

15	Details of drug(s)/Medical Device(s) as provided in the research protocol [If applicable]
16	If Regulatory Clinical Trail (CT), approval from the DCGI
17	If Clinical Trial (CT), its registration with the CTRI
18	'MTA' between collaborating center(s) [If applicable]
19	'QA/QC' Certificate for laboratory(s) used in the research project for data generation
20	If Research proposal is Multicentric, then MoU between the Institute(s)/Organization(s)
21	Details of management strategies for 'Adverse Events' related to research
22	Agreement of 'Compensation' issues (Wherever Applicable)
23	Agreement of 'Health Insurance Policies' (Wherever Applicable)
24	Agreement of 'Post Trial Access' (Wherever Applicable)
25	Agreement with 'Sponsor/Donor Agency' (Wherever Applicable)
26	Statement on Audio-Visual Consent Recording(s) [Wherever Applicable]
27	Statement on whether the Research Protocol is 'Intra-departmental /Inter-departmental/ Inter-institutional'
28	Source(s) of funding including its details
29	Signature of Principal Investigator (PI) & Co-Investigator(s) in 'Declaration Form'
30	Official seal of Principal Investigator (PI) & Co-Investigator(s) in 'Declaration Form'

31	Details of Communication address (Including Designation, Department & Organization), Contact details and Email ID of Principal Investigator & Co-Investigator(s) in the main Research Protocol including in the ICD
32	Informed Consent Document (ICD) -Part -1 [Participant Information Sheet (PIS)] in English language
33	Informed Consent Document (ICD) -Part -2 [Informed Consent Form (ICF)] in English language
34	Informed Consent Document (ICD) -Part -1 [Participant Information Sheet (PIS)] in Tamil language
35	Informed Consent Document (ICD) -Part -2 [Informed Consent Form (ICF)] in Tamil language
36	Informed Consent Document (ICD) -Part -1 [Participant Information Sheet (PIS)] in Hindi language (Wherever Applicable)
37	Informed Consent Document (ICD) -Part -2 [Informed Consent Form (ICF)] in Hindi language (Wherever Applicable)
38	'Assent' Form (Wherever Applicable)
39	Proforma/Case Record Form (CRF)/Questionnaire/Interview Guide(s)/Guides for Focused Group Discussion (FGDs) applicable to the Research Protocol [In English Version]
40	Proforma/Case Record Form [CRF]/Questionnaire/Interview Guide(s)/Guides for Focused Group Discussion (FGDs) applicable to the Research Protocol [In Tamil Version]
41	Details of 'Advertisement Materials' for enrollment of study participants [In English & Tamil Version(s)]
42	In Expedited Review: Adequate justification as per 'ICMR Guidelines -2017'
43	If 'Vulnerable Population' Involved: Scientific justification for their inclusion including how their safety, autonomy & wellbeing is taken care/maintained
44	Incentives for Study Participant(s): Provide details (If Applicable)
45	Research Study Related Cost/Expenditure (For Investigation(s)/Drug(s)/Medical Devices(s) etc.: Provide details regarding who will bear all these costs?
46	Declaration of Publication Policy: Provide detail who all are to be included as in the 'Author(s) list including their order of preference while publishing the research data

47	Statement on Storage of Sample(s): Provide details including its reuse if any/Appropriate method(s) for its discard
48	Investigator(s) Brochure (IB) [If Applicable]
49	The 'Complete Research Protocol' should reach the IEC office at least 20 days in advance to the scheduled IEC meeting including soft & 10 sets of hard copies
50	References in the 'Vancouver' format only
48	Investigator(s) Brochure (IB) [If Applicable]
49	The 'Complete Research Protocol' should reach the IEC office at least 20 days in advance to the scheduled IEC meeting including soft & 10 sets of hard copies
50	References in the 'Vancouver' format only

Institutional Ethics Committee (IEC)

All India Institute of Medical Sciences, Madurai
Ministry of Health & Family Welfare,
Government of India
Madurai, Tamil Nadu.