

**INDEPENDENT ETHICS COMMITTEE  
INDIAN MEDICAL ASSOCIATION  
(IMA)  
NEW DELHI 110002**



***Standard Operating Procedures (SOP)***

Dr. S. S. Aggarwal  
National President, IMA  
Awarded and National Roy

Dr K K Aggarwal  
Padma Shree and  
National B. C. Roy  
Award, Honorary  
Secretary IMA

## **1. OBJECTIVE:**

The objective of the Independent Ethics Committee (hereinafter referred to “**IEC**”) of Indian Medical Association (hereinafter referred to as “**IMA**”) is to ensure that all biomedical research in human subjects conducted in IMA and its affiliated wings are in accordance with the Ethical Guidelines for biomedical research on human subjects as prescribed by the Indian Council of Medical Research (hereinafter referred to as “**ICMR**”). For clinical trials, the IEC will follow the guidelines as prescribed by International Conference on Harmonization (hereinafter referred to as “**ICH**”), Good Clinical Practice (hereinafter referred to as “**GCP**”) as per Government of India and Schedule Y of the Drugs and Cosmetics Rules.

1.1 The IEC will abide by the following applicable regulatory guidelines:

1. Good Clinical Practice (GCP), as prescribed by Government of India, Drugs and Cosmetics Act and Rules i.e. Rule 122-DAA and Schedule Y of the Drugs and Cosmetics Rules
2. ICMR Guidelines for Biomedical Research on Human Subjects
3. International Conference on Harmonization (ICH) guidelines for good clinical practice and Declaration of Helsinki
4. ICMR , Guidelines for The Assisted Reproductive Technologies (Regulation)

## **2. ROLE OF INDEPENDENT ETHICS COMMITTEE (IEC)**

The IEC will review and approve all types of research proposals on human subjects received from Indian Medical Association (its states/local branches, wings, affiliated bodies) involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The goals of research, however important, would never be permitted to override the health and well-being of the research subjects.

The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - malfeasance, Confidentiality and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations (as per law) wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, for example, annual reports, final reports and site visits. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

Independent Ethics Committee has the right to discuss and review the study protocol from only IMA members or IMA affiliated medical establishments. The decision of the IEC will be final and binding.

## **3. COMPOSITION AND APPOINTMENT OF IEC**

The IEC will be constituted and its members appointed by the National President, IMA. The composition of the IEC would be multidisciplinary and multi-sectorial so that it safeguards the interests and welfare of all the sections of the community / Association. Members appointed should be familiar with the regional, social and cultural norms.

**3.1 The Composition of IEC:** The committee will comprise of not less than 10 members. The members would include: –

- a. Chairperson
- b. Vice Chairperson (National President)
- c. Member-Secretary (Hony. Secretary General)
- d. 1-2 Basic Medical Scientists
- e. 1-2 Clinicians from Various Institutes
- f. Legal Expert or Retired Judge
- g. One Social Scientist /Representative of Non-Governmental Voluntary Agency/ Social Worker
- h. One common person from the community
- i. Clinical Experts

*The committee shall have both genders representation*

**3.2 The Chairperson** of the IEC shall be from outside the Association office bearers.

**3.3 Vice Chairperson** of the IEC shall be National President of IMA.

**3.4 The Member Secretary** shall be the Honorary Secretary General of IMA. He / She shall conduct the business of the Committee.

**3.5. Basic Medical Scientist(s) and Clinicians** will be from amongst the institutions affiliated / Outsider from IMA.

#### **4. TERM OF IEC MEMBERS**

4.1 The tenure of IEC members would be for a period of 3 years

4.2 At the end of 3 years the IEC would be reconstituted by the then President of IMA.

4.3 A member can serve in the IEC for upto 3 terms (each term of 3 years).

4.4 The President can replace a member in the event of death or long-term non availability or because of any action not commensurate with the responsibilities of the members.

4.5 A member can tender resignation from the committee with proper reasons to do so by giving at least one month's notice.

4.6 The President of the Association will nominate the member of IEC who collectively have the qualifications and experience to review and evaluate the science, medial aspects, and ethics of the proposed trial.

- 4.7 Conflict of interest will be avoided when making appointments, but where unavoidable there will be transparency with regards to such interest.
- 4.8. Member can be disqualified if there is long period of non availability or inadequate contribution (absence in 3 meetings continuously without any permission).
- 4.9 All Members should maintain absolute confidentiality of all discussion during the meeting and shall sign a confidentiality form.
- 4.10. Conflict of interest should be declared by members of the IEC as and when applicable.

## **5. QUORUM REQUIREMENTS**

All decisions would be taken in the IEC meetings and not by circulation of project proposals.

A minimum of 5 members are required to compose a quorum. However, in emergent situation, a proposal may be considered by circulations.

- 5.1 The Chairperson and Member Secretary along with at least 5 other members are required to complete the quorum for a meeting.
- 5.2 Quorum will include at least one representative from following group:
- Basic Medical Scientist (preferably one Pharmacologist)
  - Clinician
  - Legal Expert
  - Lay person
  - Social Worker
- 5.3 All decisions shall be taken in meeting / and by circulation (in emergent situation) of project Proposals.

## **6. OFFICES**

- 6.1 The Chairperson will conduct all meetings of the IEC. If, for any reason which is beyond control, the Chairperson is not available, then the Vice Chairperson shall conduct the meeting and in absence of both a Working Chairperson shall be elected from the members present, who shall conduct the meeting.
- 6.2 The Member Secretary shall be responsible for organizing the meetings, maintaining the records and communicating with all the concerned members, persons, etc. He/she shall prepare the Minutes of the Meetings and get it approved by the Chairperson before communicating to the Researchers and other members of IEC, IMA.
- 6.3 For purpose of official work a dedicated staff & a helper shall be provided to Member Secretary by the President, IMA. They shall be paid remuneration through the IMA.
- 6.4 If the Member Secretary of IEC is conducting any clinical trial /study /research, then in this case, approval letter shall be signed and dated by the Chairperson of IEC.

## **7. INDEPENDENT CONSULTANTS**

Independent Ethics Committee (IEC) may call upon subject experts as Independent Consultants who may provide special review of selected research protocols, if the same is required. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They shall be required to give their views but shall not take part in the decision making process which shall be made by the members of the IEC only.

## **8. APPLICATION PROCEDURES**

- a. All proposals shall be submitted as per the prescribed format, the details of which are mentioned in **Appendix 1** (Requirements & Terms for Review of Clinical Research Study Protocol). The documents for review shall be submitted by the Principal Investigator to the Member Secretary of the IEC.
- b. The date of meeting shall be intimated to the Principal Investigator, for presentation of the protocol.
- c. The decision of IEC shall be communicated to the Principal Investigator. The decision of IEC could be one of the following: **(a)** Approved **(b)** Not approved **(c)** Resubmit with revision **(d)** Approved subject to modification.
- d. The decision of IEC shall be communicated in writing. If revision is to be made, the revised document with the required number of copies shall be submitted within the stipulated period of time as specified in the communication or before the next meeting of IEC.
- e. A non refundable prescribed fee shall be remitted along with the application **for any** Clinical Trial sponsored by a Pharmaceutical Company. (see **Annexure - I**).
- f. The Honorary Secretary General of IMA shall sign all Tripartite Clinical Trial Agreements on behalf of Indian Medical Association.
- g. SOPs can be obtained through payment of Rs. 1000/- from the office of the IEC.

## **9. DOCUMENTATION:**

For a thorough and complete review, all research proposals shall be submitted with the following documents as given in **Annexure - I** .However the documents shall contain the following information:

- 9.1 Protocol of the proposed research with name and designation of the applicant.
- 9.2 Name of the Institute/ Hospital / Field area where research shall be conducted.
- 9.3 Permission/Approval of the Head of the Department / Institution.
- 9.4 Proposal shall would be submitted with all relevant enclosures like Performa, case report forms, questionnaires, follow-up cards.
- 9.5 Ethical issues in the study and plans to address these issues.

- 9.6 Informed consent process, including patient information sheet and informed consent form in local language(s) i.e. Hindi, English & Urdu (if required).
- 9.7 For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from within the country and other countries, if available.
- 9.8 Curriculum - vitae of the Investigators and Co- investigators, updated, signed and dated.
- 9.9 Regulatory clearances from DCGI/Other Regulatory bodies wherever applicable or DCGI submission letter.
- 9.10 Source of funding and financial requirements for the project.
- 9.11 Other financial issues including those related to in
- 9.12 Insurance
- 9.13 An agreement to report Serious Adverse Events (SAE) to IEC.
- 9.14 Statement of conflicts of interest, if any.
- 9.15 Agreement to comply with the relevant national and applicable international guidelines.
- 9.16 A statement describing compensation for study participation (including expenses and access to medical care) to be given to research participants.
- 9.17 A description of the arrangements for indemnity, if applicable (in study-related injuries).
- 9.18 A description of the arrangements for insurance coverage for research participants, if applicable.
- 9.19 All significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other EC or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions would be provided.
- 9.20 Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
- 9.21 Number of trials being conducted by the investigator and the number of trials running concurrently.
- 9.22 Any other information relevant to the study.
- 9.23 Undertaking by the Principle Investigator that he/she is not conducting more than 03 drug trials as Principal Investigator.

## **10. REVIEW PROCEDURES:**

- 10.1 The meeting of the IEC, IMA shall be held on scheduled intervals and additional meetings may be held as and when required.
- 10.2 The proposals shall be sent to the members at least 14 days in advance.
- 10.3 Each proposal shall be extensively reviewed by at least two (2) members.

- 10.4 Decisions shall be taken by consensus after discussions, and whenever needed voting will be done.
- 10.5 Investigators shall be invited to offer clarifications, if required.
- 10.6 Principle Investigators shall be invited to present the proposal or elaborate on specific issues, as required by the IEC.
- 10.7 Independent Consultants/Experts shall be invited to offer their opinion on specific research proposals, as and when required.
- 10.8 The decisions shall be minuted and Chairperson's approval taken in writing.
- 10.9 The decision of the Committee shall be conveyed to the Principle Investigator by the letter, signed by the Member Secretary, responsible for handling all correspondence for the protocol, within 7-10 days of receiving satisfactory reply to questions and clarification raised upon review of the protocol. The approval letter shall essentially be as per Schedule Y to the Drugs and Cosmetics Rules for drug/device related trials.
- 10.10 Minutes of the meeting shall be recorded and the minutes shall be approved at the next meeting.

## **11. ELEMENT OF REVIEW**

Scientific design and conduct of the study shall be as per the following methodology which shall be adequately defined in the protocol.

- 11.1 Approval of appropriate Scientific Review Committees.
- 11.2 Examination of predictable risks/harms.
- 11.3 Examination of potential benefits.
- 11.4 Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
- 11.5 Management of research related injuries, adverse events.
- 11.6 Compensation provisions.
- 11.7 Justification for placebo in control arm, if any, and details of rescue medication.
- 11.8 Availability of products after the study, if applicable.
- 11.9 Patient information sheet and informed consent form in local language.
- 11.10 Protection of privacy and confidentiality.
- 11.11 Involvement of the community, wherever necessary.
- 11.12 Plans for data analysis and reporting.
- 11.13 Adherence to all regulatory requirements and applicable guidelines.
- 11.14 Competence of investigators, research and supporting staff.
- 11.15 Facilities and infrastructure of study sites.
- 11.16 Criteria for withdrawal of patients, suspending or terminating the study.

## **12. EXEMPTION FROM FULL REVIEW AND EXPEDITED REVIEW**

Based on the established criteria, proposals would qualify to be considered for **exemption from full review or expedited review**.

## **12.1 EXEMPTION FROM FULL REVIEW**

### **Categories for exemption:**

The criteria for exemption include those considered as ‘minimal risk’ suggested by the ICMR Guidelines, 2006. Exemption from review may be granted to proposals which satisfy one of the following conditions:

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

**Exemption 2:** Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement); **survey/interview procedures; observation of public behaviour, unless:** (i) information obtained is recorded in such a manner that **human subjects can be identified** directly or **through identifiers linked to the subjects** and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

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

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

**Research involving vulnerable persons will not be considered for exemption from review.**

### **Procedure for exemption from full review**

It is the responsibility of the PI to identify from the application for review, the exemption he/she believes is applicable to the research under consideration and provide a justification for the exemption(s).

The proposal will be screened by the IEC office and after screening, the IEC office shall sent the same to the Chairperson and Member Secretary for technical review and approval of exemption from full ethical review. The IEC members can request the PI for any clarifications on the proposals.



If a decision to exempt the proposal from full IEC review is taken by The Chairperson and the Member-Secretary, it would be notified by the Member Secretary to the PI in writing giving the provision under which the exemption has been granted. If the Chairperson and Member Secretary decide that the proposal cannot be exempted from full review, a recommendation for expedited or full review may be made.

List of proposals exempted from review would be provided to the Chairperson of the IEC prior to the next IEC meeting.

## **12.2 EXPEDITED REVIEW**

Proposals that involve no more than ‘minimal risk’ and those that do not satisfy the criteria for exemption will be eligible to apply for expedited review. Research involving vulnerable persons may be considered for expedited review.

### **Categories for expedited review**

#### **a. Already approved studies:**

- i. Follow-up reports of proposals previously approved either by expedited or full review.
- ii. Minor alterations (which do not result in any increase in risk) to studies which have previously been approved either by expedited or full review.
- iii. Proposals which have already undergone full ethical review by any other national/local Independent Ethics Committee and have received approval.

#### **b. New Studies:**

- i. Research on individual or group characteristics or behaviour (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, human factors evaluation or quality assurance methodologies with clear identifiers to the subject.
- ii. Research involving clinical studies of drugs and medical devices where these (drugs and devices) have already been approved (except when studying drug interaction or conducting trials involving vulnerable population)
- iii. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture from healthy adults and children.
- iv. Prospective collection of biological specimens for research purposes by noninvasive means.
- v. In emergency situations like serious outbreaks or disasters where full review of the research is not possible. Such research can only be approved as a pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated on the basis of the findings of the pilot study.

- vi. Research on interventions during outbreaks or disasters may be considered for expedited review provided a Data Safety Monitoring Board (DSMB) is constituted to review the data.

### **PROCEDURE FOR EXPEDITED REVIEW**

Once the proposal has been screened by the IEC office and found to satisfy the criteria for expedited review, the expedited review may be undertaken by the two persons appointed by the Chairperson - one IEC, IMA member and one external member.

The guidelines for review are same as those to be followed for full review. If required, expert opinion may be sought, keeping in mind confidentiality, but the expert will not play any role in making the final decision.

The reviewers may approve or conditionally approve the study, or may recommend it for full review. If there is disagreement between reviewers, Member Secretary along with the Chairperson will make the final decision. For expedited review, the reviewers can contact the PI for clarifications through the Member Secretary. The decision of the expedited review would be sent in writing by the Member Secretary to the PI.

A list of research proposals considered for expedited review and the outcome shall be provided to the Chairperson, IEC. A record must be maintained of category under which the expedited review was justified.

### **13. AMENDMENTS TO PROTOCOL AND THEIR APPROVAL**

- 13.1 Any deviation /change to a protocol shall be considered as a protocol amendment .The amendments shall be classified as *Major or Minor*.
- 13.2 Urgent amendment necessary to eliminate immediate hazards to the trial subject (s). In such a case, the Principal Investigator shall make necessary amendments and convey the same to the IEC.
- 13.3 Requirements for amendments are mentioned in **APPENDIX ‘I’**.
- 13.4 All the Protocols and amendments submitted to it in its meetings. The protocols shall be sent to all the members.
- 13.5 All the members participate in discussion for approval of any Protocol or amendment.

### **14. IEC FEES**

14.1 The fee for industry sponsored projects/trials shall be as follows:

- |  |                |
|--|----------------|
| a) Fee for initial approval of protocol:   | Rs. 1,00,000/- |
| b) Fee for review of each amendments:  | Rs. 25,000/-   |
| c) Fee for review of each Serious Adverse events at site:  | Rs. 15,000/-   |
| d) Fee for internationally funded collaborative studies Rs (INR)                                   | \$ 5,000/-     |
| e) Free for Academic study and approval for abstract<br>(committee may decided to give concession) | Rs.20,000/-    |
| TA/DA per meeting per member   | Rs.3,000/-     |

14.2 The fee structure can be revised from time to time as required.

## **15. SUB-COMMITTEE(S) OF IEC**

15.1 Amendments / SAE / AE: A sub-committee would examine all amendments, adverse events and serious adverse events reported / submitted to the IEC and present them to the full IEC for comments and approvals. The investigators would not be required to be present while these are discussed at the IEC meeting.

15.2 Compensation. A sub-committee would examine issues related to subject compensation.

New sub-committees may be constituted as and when required.

## **16. WORKSHOP**

The IEC shall organize atleast one workshop during its tenure to spread awareness on ethical issues related to biomedical research amongst a variety of stakeholders.

## **17. WEBSITE**

The IEC shall have a separate space within the website of the institution (Indian Medical Association) i.e. www.\_\_\_\_\_

## **18. PRINCIPAL INVESTIGATOR RESPONSIBILITY**

**Principle investigator shall be responsible for keeping the IEC informed about the ongoing study.**

18.1 A Principal Investigator shall not be concurrently running more than three trials / studies/projects.

18.2 Reports are to be submitted annually for review to IEC.

18.3 Final report would be submitted at the end of study.

18.4 All SAEs and the interventions undertaken would be intimated.

18.5 Protocol deviation, if any, would be informed with adequate justifications.

18.6 Any amendment to the protocol would be resubmitted for renewed approval.

18.7 Any new information related to the study would be communicated.

18.8 Premature termination of study would be notified with reasons along with summary of the data obtained so far.

18.9 Change of investigators / sites would be informed.

18.10 To be kept information of study completion and discontinuation with reasons.

18.11 To submit justification for approval to restarts studies discontinued earlier.

18.12 The PI must register the Clinical study with CTRI (ICMR) within 2 weeks of IEC approval letter and inform the IEC of the CTRI registration number.

## **19. DECISION-MAKING & COMMUNICATING OF DECISION TO PRINCIPAL INVESTIGATOR**

**In making decision on application for the ethical review of research proposal the IEC shall take the following into consideration:**

- 19.1 Members shall discuss various issues before arriving at a consensus decision.
- 19.2 Decisions shall be taken by IEC members only. Experts will give their opinion, but will have no voting rights.
- 19.3 A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this shall be indicated to the Chairperson prior to the review of the application and shall be recorded in the minutes of meeting also.
- 19.4 Decisions shall be in the form of **(a)** Approved **(b)** Not approved **(c)** Resubmit with revision **(d)** Approved subject to modification / clarification. Decisions shall be communicated in writing by the Member Secretary to Principal investigator with reasons wherever required.
- 19.5 The format of the approval is given in **Appendix 'II'** or as per study requirement.
- 19.6 Modified proposals may be reviewed by an expedited review through identified members.
- 19.7 A negative decision on an application shall be supported by clear stated reason.
- 19.8 In cases of conditional decision, clear suggestions for revision and the procedure for having the application re-reviewed shall be specified.
- 19.9 The investigator shall have the right to appeal to the Appellant Body. In this case, the Appellant Body shall be President, IMA.
- 19.10 An investigator who is a member of the IEC can clarify any points raised by the other members about his/her proposal, but must withdraw from the meeting during the period when decision/voting on his/her proposal being considered by the IEC.

## **20. INFORMED CONSENT /AUDIO VEDIO CONSENTING**

The IEC shall have a uniform template of patient information sheet and patient consent/assent form. The investigators shall be required to submit the above mentioned documents in the IEC' template format and the same shall be obtained by the investigators from the office of the IEC **(As given in Appendix III, IV & V)**

- 20.1 With reference to the notification of Drug Controller General of India, Directorate General of Health Services, New Delhi dated 19<sup>th</sup> November, 2013 regarding Audio-visual recording of the informed consent process, it is now mandatory to take audio –visual consent from all

clinical trial patients with immediate effect, IEC directs all PIS to adhere to the DCGI guidelines related to the new consenting process in all the ongoing clinical trial.

## 21. VULNERABLE GROUP AS RESEARCH PARTICIPANTS

Efforts may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- a) Research on genetic should not lead to **racial inequalities**.
- b) Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them.
- c) Right and welfare of **mentally challenged and mentally differently able person** who are incapable of giving informed consent or those with behavioral disorder must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedure. The entire consent process should be properly documented
- d) Adequate justification is required for the involvement of participants such as prisoners, student, subordinated, employees, service personnel etc. who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.

## 22. ADVERSE EVENT

22.1 A serious adverse shall be reported to the IEC within 24 hrs day from the date of occurrence.

22.2 The serious adverse event report shall contain the following

- i. Patients details - Initials and other relevant identifier (hospital /OPD record number etc.)
- ii. Suspected Drug
- iii. Indication (s) for which suspected drug was prescribed of tested
- iv. Daily dose and regimen (specify unit of measure, e.g. mg. ml. mg / kg)
- v. Route of administration
- vi. Starting date and time or duration of treatment
- vii. Date of reaction
- viii. Stop date and time of duration of reaction
- ix. De-challenge and re-challenge information
- x. Information on recovery and any sequel, result of specific test and /or treatment.
- xi. Medical history allergy, drug or alcohol abuse, family history, findings from special Investigators
- xii. Clinical investigator details –Name, address, telephone, E-mail
- xiii. Signature of the investigator

- xiv. Original protocol
- xv. DCGI approval
- xvi. IEC approval
- xvii. Full case sheet
- xviii. ADR reporting form
- xix. Trial form /Performa
- xx. One member of the research team to be available at the time of meeting of sub-committee
- xxi. Any other relevant document required to review SAE by sub-committee of the IEC
- xxii. Inform the date and time of meeting to the Principal Investigator.
- xxiii. Details of the Performa/Trial form indicating the investigations performed before/after the administration of each dose. The Investigational Product (including the PT/INR etc.)
- xxiv. The details of risk factor depending on the seriousness or severity of disease, presence of the co-morbidity and during of disease the subject at the time of enrollment at the time of clinical trial between the scale of 0.5 – 4.0 as per the compensation formula decided by IEC (available on the website CDSCO.nic.in)

### **23. RECORD KEEPING AND ARCHIVING**

All documents and communication of the IEC shall be dated, filed and archived. Documents shall be archived for a minimum period of five (5) years following the completion of the study.

Documents that are to be filed and archived include but are not limited to:

- 23.1 Curriculum Vitae (CV) of all members of IEC.
- 23.2 Copy of all study protocols with enclosed documents, Progress Reports, and SAEs.
- 23.3 Minutes of all meetings duly approved by the Chairperson.
- 23.4 Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- 23.5 Copy of all correspondence with members, researchers and other regulatory bodies.
- 23.6 The constitution, written standard operating procedures (SOPs) of the IEC and periodical /annual reports.
- 23.7 Records of all income and expenses of the IEC, IMA, including allowances and reimbursements made to the IEC members
- 23.8 The agenda of the IEC meeting
- 23.9 Correspondence by IEC members with applicants and concerned parties regarding application, decision, follow up etc.
- 23.10 A copy of the decision /approval and any advice or requirements sent to an applicant.

23.11 All written documents received during the follow up.

23.12 Final report of the approved projects.

23.13 A register shall be maintained for proposed study. All the details of protocols like date of receipt, date of discussion, date of approval, follow up and date of final reports shall be recorded in the said register.

#### **24. TABLE OF ABBREVIATIONS**

• CRO	Contract Research Organization
• CTRI	Clinical Trial Registry of India
• CV	Curriculum Vitae
• DSMB	Data Safety Monitoring Board
• GCP	Good Clinical Practice
• ICD	Informed Consent Document
• ICF	Informed Consent Form
• ICH	International Conference of Harmonization
• ICMR	Indian Council of Medical Research
• IEC	Independent Ethics Committee
• IRB	Institutional Review Board
• IMA	Indian Medical Association
• OTC	Over the Counter
• PIS	Patient Information Sheet
• PI	Principal Investigator
• SOP	Standard Operating Procedure
• SAE	Serious Adverse Event
• NDA	New Drug Application
• ADR	Adverse Drug Reaction
• HRPP	Human Research Protection Programmes
• FWA	Federal Wide Assurance
• OHRP	Office for Human Research Protections
• HHS	Health and Human Services

#### **25. UPDATING IEC, IMA MEMBERS**

25.1 All relevant new guidelines shall be brought to the attention of the members.

25.2 Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware about the latest developments in this area.

25.3 Any new update or notification issued by Drug Controller General of India, (DCGI) Directorate General of Health Services(DHS), New Delhi from time to time shall be followed by IEC, IMA.

## **26. ACCEPTANCE AND APPROVAL OF STANDARD OPERATING PROCEDURE (SOP)**

This Standard Operating Procedure (SOP) has been discussed, accepted and approved by all the members of the Independent Ethics Committee of Indian Medical Association and on confirmation, the same has been duly approved by the Working Committee & Central Council of IMA. Any change or update, as recommended by IEC shall be required to be approved by Working Committee and Central Council of IMA.

\_\_\_\_\_  
Member (Secretary),  
Independent Ethics Committee

\_\_\_\_\_  
Date:



## APPENDIX I

### **GUIDELINES FOR SUBMISSION OF PROPOSALS TO THE ETHICAL COMMITTEE**

#### **(A) List of Document to be Submitted to IEC for Drug Trial Protocol.**

**The \_\_\_\_hard copy of protocol with each document & 10 soft copy of CD**

1. Application forwarded by the HOD/institution
  2. Invitation Letter from the sponsor
  3. Summary of the protocol
  4. Index of documents with stickers at appropriate places
  5. C.V of the Principal Investigator & Co-Investigator updated, signed and dated.
  6. ICP-GCP Certificate of PI
  7. DCGI clearance
  8. Indemnity Bond/Insurance Coverage
  9. Written Informed Consents from Hindi, English & local language
  10. Patient Information Sheet.
  11. Funding / Financial disclosure.
  12. Copies of the Protocol
  13. Crossed cheque/ Draft worth Rs.\_\_\_\_\_/ - in the name of Indian Medical Association Account  
IEC
  14. Clinical Trial Agreement (CTA)
  15. CTRI Registration number for the study
  16. Soft copy of approved protocol (PDF format in CD)
  17. Contact no. and E-mail ID
  18. One file folder
- All documents are found to be complete:
    - a. Proposal is received at least 2-weeks prior to the date for Ethical Committee Meeting.
    - b. No more than 12 projects have already been received for IEC meeting.
  - **List of documents for Amendments in already approved protocols:**
    - a) Summary of the amendment ( to be incorporated )
    - b) Processing Fees \_\_\_\_\_ /-
    - c) Copies of detailed documents.

#### **(B) List of Document to be Submitted to IEC for Academic Study:**

1. Application forwarded by the HOD/Institution. (signed with stamp)
2. Summary of the protocol
3. Index of documents with stickers at appropriate places
4. Recommendations letter from Departmental Scientific Committee consisting of three faculty members other than Principal Investigator and Co-investigator on departmental letter head with date. **(signed with stamp)**
5. Current C.V of the Principal Investigator & Co-Investigator updated, signed and dated .
6. List of study team (signed with stamp)
7. Written Informed Consents in both Hindi & English.
8. Patient Information Sheet shall be in Hindi, English and local language
9. Protocol
10. Crossed cheque/ Draft worth **Rs.\_\_\_\_\_/-** in the name Indian Medical Association Account IEC.
11. Budget details
12. CTRI Registration number (After IEC approval )
13. Soft copy of approved protocol (PDF format in CD)
14. Contact no. and E-mail ID
15. One file folder

**(C) List of documents required for Serious Adverse Event in already approved protocol:**

- i. Patients details - Initials and other relevant identifier (hospital /OPD record number etc.)
- ii. Suspected Drug
- iii. Indication (s) for which suspected drug was prescribed of tested
- iv. Daily dose and regimen (specify unit of measure ,e.g.mg.ml.mg/kg)
- v. Route of administration
- vi. Starting date and time or duration of treatment
- vii. Date of reaction
- viii. Stop date and time of duration of reaction
- ix. De-challenge and re-challenge information
- x. Information on recovery and any sequel, result of specific test and /or treatment .
- xi. Medical history allergy, drug or alcohol abuse, family history, findings from special investigators
- xii. Clinical investigator details –Name ,address, telephone ,E-mail
- xiii. Signature of the investigator
- xiv. Original protocol
- xv. DCGI approval

- xvi. IEC approval
- xvii. Full case sheet
- xviii. ADR reporting form
- xix. Trial form /Performa
- xx. One member of the research team to be available at the time of meeting of sub committee
- xxi. Any other relevant document required to review SAE by sub committee of the IEC
- xxii. Inform the date and time of meeting to the Principal Investigator.
- xxiii. Details of the Performa/Trial form indicating the investigations performed before/after the administration of each dose. The Investigational product (including the PT/INR etc.)
- xxiv. The details of risk factor depending on the seriousness or severity of disease, presence of the co-morbidity during and during of disease the subject at the time of enrollment at the time of clinical trial between the scale of 0.5 – 4.0 as per the compensation formula decided by IEC (available on the website CDSCO.nic.in
- xxv. Crossed cheque/ Draft worth **Rs. \_\_\_\_\_/- in** the name of Indian Medical Association Account IEC

(ON IEC LETTER HEAD)

ANNEXURE II

To,

Dr. \_\_\_\_\_  
Department of \_\_\_\_\_

Sub: Protocol no

Dear Dr.

The Independent Ethics Committee of Indian Medical Association New Delhi 110 002 has reviewed and discussed your application to conduct the clinical trial entitled “.....” on .....(dated)

The following documents were reviewed:

1. Trial Protocol (including protocol amendments dated \_\_\_\_\_ version No. \_\_\_\_\_.
2. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
3. Investigator’s Brochure dated \_\_\_\_\_ version No. \_\_\_\_\_
4. Proposed methods for patient accrual including advertisement etc. proposed to be used for the purpose.
5. Principal Investigator’s current C.V.
6. Insurance Policy/compensation for participation and for serious adverse events occurring during the study participation.
7. Investigator’s Agreement with sponsor

The following members of the ethics committee were present of the meeting held on (date, time, place).

\_\_\_\_\_ Chairman of the ethics committee  
\_\_\_\_\_ Member Secretary of the ethics committee  
\_\_\_\_\_ name of each member with designation

We approve the trial to be conducted in its presented form.

The Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and Patient Information/Informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Members Secretary  
Independent Ethics Committee

**ANNEXURE III**

**Name of Hospital**

**(Department of \_\_\_\_\_)**

**PATIENT INFORMATION SHEET**

You are being invited to participate in a research study.

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

**STUDY INFORMATION**

**Protocol Title:**

**Principal Investigator(s):**

*(Insert the identity of other health professionals involved in the study or the funding organization associated with the research. Delete this section if this is an investigator-initiated study without specific funding.)*

**PURPOSE OF THE RESEARCH STUDY**

You are being invited to participate in a research study of *(state what is being studied)*. We hope to learn *(state what the study is designed to discover or establish)*. You were selected as a possible subject in this study because *(explain why patient is being selected)*

This study will recruit *(insert number of subjects)* subjects from *(state whether from the Principal Investigator's institution, or multiple institutions)* over a period of *(state recruitment and/or study period)*. About *(state number of subjects recruited in this or previous related studies)* subjects will be involved in this study.

Any samples of tissues, blood and/or body fluids obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding *(Insert intended duration of storage)*, and will be destroyed after completion of the study, unless you have signed a consent form to donate the samples to *(insert name of repository)*.

When your participation in the study ends, you will no longer have access to *(the study medication/device)*, unless special additional arrangements are made by the Principal Investigator.

**STUDY PROCEDURES AND VISIT SCHEDULE**

If you agree to take part in this study, you will be randomised to receive *(expand with details of study*

as necessary). Randomisation means assigning you to one of (*insert number of study groups*) groups by chance, like tossing a coin or rolling dice. (*Delete para if there is no randomization.*)

If you agree to take part in this study, you will be asked to (*insert brief explanation of study procedures here*). Your participation in the study will last (*insert length of time subject will be required for the study*). You will (*take the study medication / use the study device*) for about (*insert number of times study intervention will be performed*) and be followed up for (*state length of time of follow-up within the study*). You will need to visit the doctor's office (*state number of times*) times in the course of the study.

### **Schedule of visits and procedures:**

Visit 1:

Visit 2, 3 (Weeks \_\_, \_\_) etc.

Final Visit (Week \_\_)

Follow-up: The follow-up part consists of (*state number of contacts*)

### **Additional Study Procedures**

(*Insert additional procedures that must be performed.*)

### **Additional Blood Tests**

(*State how many blood specimens are required and the amount in teaspoons as part of this study.*)

## **YOUR RESPONSIBILITIES IN THIS STUDY**

If you agree to participate in this study, you should (*choose applicable points*):

- Take the study drug as instructed and follow the advice given to you by the study team. (*if device, explain what is required for study compliance*).
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital (*insert number of visits*) and undergo all the procedures that are outlined above.

## **WITHDRAWAL FROM STUDY**

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, or the study medication is stopped for any reason,

- (*Add anticipated consequences, if any, of discontinuing the study drug or device*).
- (*Clearly state the protocol-specific termination procedures*).
- (*Return all study-related supplies, including unused study drug*).

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons: (*You may use these reasons and/or add some of your own.*)

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- Pregnancy (*if applicable.*)
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

### **WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY**

The study is being conducted because (the intervention or device) is not yet proven to be a standard (investigation, treatment) in subjects with (condition under investigation in this study). We hope that your participation will help us to determine whether (investigation or treatment) is equal or superior to existing (investigation or treatment).

Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. (*Modify as relevant for your study.*)

Although (Investigation or Treatment) may be part of standard medical care, in this study this / these procedure(s) are being performed for the purposes of the research.

### **POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES**

*There are risks, discomforts and inconveniences associated with any research study. These deserve careful thought.*

- Describe the discomforts and inconveniences reasonably expected.
- Describe the expected adverse outcomes (to exclude what is possible but unexpected).
- If there is a washout period, describe the risks of discontinuing medications.
- Describe any reasonably foreseeable risks. Note that if this is a placebo-controlled study, there may exist the risk that the disease/condition may go untreated and the subject's condition may worsen.
- Include a statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
- Note: this section should also describe the risks associated with other medications used in the study, other procedures done (i.e., venipuncture, concomitant medications, exposure to radiation, etc.).

### **POTENTIAL BENEFITS**

If you participate in this trial you may reasonably expect to benefit from the trial (investigation / intervention / drug) in the following way: (*explain how subject might benefit*)

## **OR**

There is no assurance you will benefit from this study. However, your participation may contribute to the medical knowledge about the use of this (medication / device / intervention / investigation).

### **ALTERNATIVES**

*Delete or modify as necessary.* If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be (investigation / treatment / procedure).

This procedure has the following potential benefits:

(Insert list of possible benefits of the “standard” alternative).

and the following potential risks:

*(Insert list of possible risks from the “standard” alternative*

### **IMPORTANT INFORMATION FOR WOMEN SUBJECTS**

*(Delete or modify as necessary).* The effect of *(the study drug/intervention/investigation)* on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study. If you become pregnant during this study, you must stop taking *(the study drug)* and call your doctor or the Principal Investigator immediately.

### **SUBJECT'S RIGHTS**

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you or your legal representative will be informed in a timely manner by the Principal Investigator or his/her representative.

You have the right to refuse to allow your tissues to be studied now or saved for future study. By signing and participating in the trial, you do not waive any of your legal rights to revoke your consent and withdraw from the trial at any time.

### **CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS**

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, the Sponsoring company *(Name of company, if relevant)*, Regulatory Agencies, Institution Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you or your legal representative is authorizing such access to your



study and medical records.

Data collected and entered into the Case Report Forms are the property of (*Institution or Company*). In the event of any publication regarding this study, your identity will remain confidential.

### **COSTS OF PARTICIPATION**

If you take part in this study, the following will be performed at no charge to you: (*Insert list of procedures / drugs/ tests for which the subject will NOT pay*). You will not receive any compensation for participating in this study.

### **RESEARCH RELATED INJURY AND COMPENSATION**

The Hospital does not make any provisions to compensate trial subjects for research related injury. However, you would be treated for the same at no additional costs at this hospital.

### **WHO TO CONTACT IF YOU HAVE QUESTIONS**

If you have questions about this research study and your rights or in the case of any injuries during the course of this study, you may contact the Principal Investigator (*Insert Name and contact Details including place and phone numbers here*).

<b>CONSENT BY RESEARCH SUBJECT</b>	
<b>Details of Research Study</b>	
<b>Protocol Title:</b> <i>Use the full protocol title as used in the IRB Application</i>	
<b>Principal Investigator:</b> <i>Include full name, address and phone number</i>	
<b>Subject's Particulars</b>	
Name:	NRIC No.:
Address:	
Sex: Female/Male	Date of birth _____ dd/mm/yyyy
Race: Chinese/ Malay/ Indian /Others (please specify) _____	
<b>Part I – to be filled by patient</b>	

I, \_\_\_\_\_ (NRIC/Passport No. \_\_\_\_\_)

(Name of patient)

**agree / do not agree** to participate in the research study as described and on the terms set out in the Patient Information Sheet. The nature of my participation in the proposed research study has been explained to me in

\_\_\_\_\_ by Dr/Mr/Ms \_\_\_\_\_

(Language / Dialect)

(Name of healthcare worker)

I have fully discussed and understood the purpose and procedures of this study. I have been given the Patient Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

I also give permission for information in my medical records to be used for research. In any event of publication, I understand that this information will not bear my name or other identifiers and that due care will be taken to preserve the confidentiality of this information.

\_\_\_\_\_  
[Signature/Thumbprint (Right / Left) of patient]

\_\_\_\_\_  
(Date of signing)

**Part II – to be filled by parent / legal guardian, where applicable**

I, \_\_\_\_\_ hereby give consent for the above patient to participate in the (parent / legal guardian) proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

\_\_\_\_\_  
[Signature/Thumbprint (Right / Left) of parent /legal guardian] (Date of signing)

**Part III – to be filled witness, where applicable**

An impartial witness should be present during the entire informed consent discussion if a subject or the subject's legally acceptable representative is unable to read. After the written informed consent form and any written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally representative has orally consented to the subject's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form.

Witnessed by: \_\_\_\_\_ (Name of witness) \_\_\_\_\_ (Designation of witness)

\_\_\_\_\_  
(Signature of witness) (Date of signing)

**Part IV– Investigator's Statement**

I, the undersigned, certify to the best of my knowledge that the patient/patient's legally acceptable representative signing this informed consent form had the study fully explained and clearly understands the nature, risks and benefits of his/her / his ward's / her ward's participation in the study.

\_\_\_\_\_  
Name of Investigator  
Date

\_\_\_\_\_  
Signature

**ANNEXURE IV**

(Department of \_\_\_\_\_)

**INFORMED CONSENT FORM**

S. No.

Date

Patient's Name

Name Parent/Guardian/LAR:

Age:

Sex:

I have been explained the details of study entitled "....." and my question (s) regarding the study have been answered to my satisfaction in a language understood by me.

1. I understand that I have the right to withdraw from the study at any time and time and to decline to answer any particular question.
2. I understood that my participation in this study is confidential and that no material that could identify me will be used in the analysis and in any reports based on this study.
3. I consent to my blood (a maximum of 5 ml) being drawn for the purpose of this study .I understand that on completion of the study or if I withdraw from the study, my blood sample (s ) will be destroyed. I also understand that there is any problem with any of the blood tests or measurement taken, I will be informed and the report will be kept confidential.

I hereby provide the my consent to take part in the study entitled ".....".

Signature/ Thumb Impression of volunteer      Subject/LAR

Signature of witness/ Signature of Guardian

Signature of investigator

Name & Address of Witness/Guardian

This SOP is applicable for all projects submitted to IEC for review and approval, and is approved by all of its members as below:

S.no.	Name	Signature with date
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		