INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures

Cancer Institute (WIA)
Adyar, Chennai 600 020
Phone: 044-22209150 Extn: 135
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## Mission Statement

The mission of Institutional Ethics Committee (IEC), Cancer Institute (WIA), Chennai, is to protect the rights, safety and well-being of research participants in cancer clinical trials and other academic studies conforming to high standards of ethics and with integrity.
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**Date:** June 13, 2018
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INSTITUTIONAL ETHICS COMMITTEE (IEC)

1) **Policy:** IEC is constituted as an independent body to oversee the adherence of ethical principles in all research activities at the institute conforming to current regulations, guidelines and standards.

2) **Objective:** The objective of the standard operating procedures (SOP’s) is the ethical principles, regulations and the process followed by the ethics committee at the Cancer Institute (WIA), conforming to the underlying policy.

3) The Cancer Institute (WIA) established the ethics committee in June 2002 to review, approve, monitor Clinical Trials and Basic Medical and Health Research at the Institute. It was re-constituted in accordance with Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945 and registered with Drugs Controller General of India as per Rule 122 DD in April 2013 as an Institutional Ethics Committee (IEC).

The IEC is registered at the following address:

Institutional Ethics Committee,  
Cancer Institute (WIA),  
East Canal Bank Road  
Gandhi Nagar, Adyar,  
Chennai, Tamil Nadu-600 020

The registration details of IEC are as follows:

Re-registration number: ECR/235/Inst/TN/2013/RR-16
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<td>Chakradhara Padala</td>
<td>Dr. R. Swaminathan</td>
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<td>Designation</td>
<td>Clinical Research Associate</td>
<td>Member Secretary</td>
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4) The IEC at the Cancer Institute (WIA) functions in accordance with Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945, National Ethical Guidelines for Bio-Medical and Health Research Involving Human Participants, Good Clinical Practice Guidelines for Clinical Trials in India and other applicable national, international regulations and guidelines as set out in this SOP. The registration of IEC is usually valid for 3 years. Re-registration of IEC should be done 3 months from the date of expiry.

5) All the members in the IEC are appointed on a voluntary basis. The list of IEC members with role/ designation in the committee and their affiliation with Cancer Institute (WIA) are given in Annexure 1.1 of this SOP.

6) The IEC has the authority to approve, advise modifications or to disapprove research activities involving human subjects in adherence to ethical principles. IEC has also got the authority to suspend or terminate approved study for non-compliance of study protocol or regulations.

7) As a principle, IEC at the institute does not levy any fee for reviewing any research proposal including clinical trials (sponsored and academic) and other prospective/retrospective studies in all scientific disciplines. However, the institute may receive grant for covering the costs of conduct of the study.

8) All communications requiring IEC attention should be addressed in writing to The Chairman/Member Secretary, IEC. Those requiring a discussion will be tabled in the IEC meeting. Every communication received will be acknowledged and action taken will be minuted by IEC Secretariat.

9) All complaints about IEC functioning should be addressed in writing to the Director, Cancer Institute (WIA), Chennai for redressal.

10) All the stakeholders of research activities (IEC members, principal investigators and research staff) at the Cancer Institute (WIA) are required to comply with the following ethical principles.
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<tr>
<td>Chakradhara Reddy Padala</td>
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**Ethical Principles**

All research involving human subjects should be conducted strictly in accordance with the ethical principles outlined in the current revision of Declaration of Helsinki. They are,

**Preamble:**

1) The World Medical Association (WMA) has developed the Declaration of Helsinki as statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

2) The declaration is intended to be read as whole and each of its constituent paragraphs should be applied with consideration for all other relevant paragraphs. Consistent with the mandate of world medical association (WMA), the declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

**General Principles:**

3) The declaration of Geneva of the WMA binds the physicians with the words, “The health of my patient will be my first consideration,” and the international code of medical ethics declares that, a physician shall act in the patient’s best interest when providing medical care”.

4) It is the duty of physician to promote and safeguard the health, well-being and rights of patients including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.

5) Medical progress is based on research that ultimately must include studies involving human subjects.

6) The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (Methods, procedures and treatments). Even the best proven intervention must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
7) Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8) While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9) It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other healthcare professionals and never with the research subjects, even though they have given consent.

10) Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this declaration.

11) Medical research should be conducted in a manner that minimizes possible harm to the environment.

12) Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or health volunteers requires the supervision of a competent and appropriately qualified physician or other healthcare profession.

13) Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14) Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in research study will not adversely affect the health of the patients who serve as research subjects.
15) Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16) In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17) All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individual of groups affected by the condition under investigation.

Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18) Physicians may not be involved in a research study involving human subjects unless they are confident that risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19) Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specially considered protection.

20) Medical Research with a vulnerable group is only justified if the research is
responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21) Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of scientific literature, other relevant sources of information and adequate laboratory and, as appropriate animal experimentation. The welfare of animals used for research must be respected.

22) The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflict of interest, incentive for subjects and information regarding provisions for treating and or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23) The research protocol must be submitted to the IEC for consideration, comment, guidance and approval before study begins. The committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this declaration.
The IEC must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about co-enrollment into concurrent/sequential study and any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researcher must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24) Every precaution must be taken to protect the privacy of research subjects and confidentiality of their personal information.

Informed Consent

25) Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26) In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflict of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information the physician or another appropriately qualified individual must then seek the potential subjects freely given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
All medical research subjects should be given the option of being informed about general outcome and results of the study.

27) When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subjects is in dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28) For potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent and the research entails only minimal risk and minimal burden.

29) When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek the assent in addition to the consent of the legally authorized representative. The potential subject’s dissent must be respected.

30) Research involving subjects who are physically and mentally incapable of giving consent for example unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative, if no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or legally authorized representative.

31) The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient’s decision
to withdraw from the study must never adversely affect the patient-physician relationship.

32) For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33) The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo or no intervention is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-trial Provisions

34) In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.
Research Registration and Publication and Dissemination of Results:

35) Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36) Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflict of interest must be declared in the publication. Reports of research not in accordance with the principles of this declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice:

37) In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent form the patient or legally authorized representative may use an unproven intervention if in the physician’s judgment it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all case new information must be recorded and where appropriate made publicly available.

11. Responsible Person(s): IEC members and Head of the Cancer Institute (WIA)
12. References:

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants 2017

3) National Ethical Guidelines for Bio-medical and Health Research Involving Children 2017

4) National Ethical Guidelines for Stem Cell Research 2017

5) Good Clinical Practice Guidelines for Clinical Trials in India.

6) Handbook for Applicants & Reviewers of Clinical Trials of New Drugs in India 2017

7) ICH - E6 (R2): Good Clinical Practice (GCP).

8) Clinical Trials Registry-India (CTRI).

9) World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants.
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<th>Sr. No.</th>
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<th>Affiliation of member with institute that has constituted the Ethics Committee</th>
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E mail: vimathan1995@gmail.com  
Mobile: 9840038637 | Chairman | Not affiliated to Cancer Institute (WIA) |
| 2       | Dr. R. Swaminathan | M.Sc., Ph.D. (Statistics), Ph.D. (Epidemiology) | Assistant Director, Professor & Head, Dept. of Epidemiology, Biostatistics & Cancer Registry, Cancer Institute (WIA), Chennai | Cancer Institute (WIA), 38, Sardar Patel Road, Chennai 600 036  
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<td>4</td>
<td>Dr. V.K. Ramadesikan</td>
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<td>8</td>
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<td>Mrs. Ranganayaki Kumar</td>
<td>B.A, D.A.M</td>
<td>Social Worker Chennai</td>
<td>50, Karapagam Avenue III Street, Chennai -600028 Email: <a href="mailto:rangikumari@gmail.com">rangikumari@gmail.com</a> Mobile:9841094282</td>
<td>Lay Person</td>
<td>Not Affiliated to Cancer Institute(WIA)</td>
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1) **Purpose:** General procedure to constitute the ethics committee.

2) **Scope:** Applicable to Cancer Institute (WIA).

3) **Procedure:**

1. Director, Cancer Institute (WIA) is the institutional authority to constitute the ethics committee.

2. The ethics committee should be constituted in accordance with Appendix VIII of Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Good Clinical Practice Guidelines (GCP) for clinical trials in India.

3. The Director will ensure that the ethics committee is constituted in accordance with Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 requirements, National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants and Good Clinical Practice Guidelines for Clinical Trials in India.

4. Director will invite the members from medical, non-medical and non-scientific fields including lay person to the join the ethics committee by sending the official invitation letters.

5. The IEC can have a maximum of 15 members and a minimum of 7 members.

6. Members will confirm their acceptance to the Director by providing all the required documentation for the membership of the ethics committee i.e. Curriculum Vitae with details of education, experience and training undergone.

7. One of the members of the ethics committee who is from outside the institution would be appointed as Chairman. Member secretary can be from the same institution for operational convenience.

8. Chairman, member secretary and members of the ethics committee should undergo detailed training program on National Ethical Guidelines for Bio-Medical and Health Research Involving Human Participants, Schedule Y of Drugs and
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<td>Name</td>
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<td>Designation</td>
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Cosmetics Act 1940 and Rules 1945 as amended from time to time and on Good Clinical Practice Guidelines for Clinical Trials in India and other applicable national and international regulations and guidelines.

9. Members should be conversant with the provisions for clinical trials under Schedule Y of Drugs & Cosmetics Act 1940 and Rules 1945, National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants, Good Clinical Practice Guidelines for Clinical Trials in India and other regulatory requirements.

10. Ethics committee should establish its own policies and standard operating procedures for its operations and should have an office space, required infrastructure and staff for an independent functioning.

11. Ethics committee should be registered with Drugs Controller General of India as per Rule 122 DD of Drugs & Cosmetics Act 1940 & Rules 1945 to function as an institutional ethics committee.

12. Ethics committee should be accredited with National Accreditation Board for Hospitals & Healthcare Providers effective 01 January 2018.

13. Director authorizes the independence of the ethics committee in its functioning and decision making.

14. The member secretary will conduct the proceedings of the ethics committee in accordance with current regulations, guidelines, policies and standard operating procedures.

15. At regular intervals the Director will review the composition and functioning of the ethics committee with respect to the scope of research work, human subject protection, regularity, compliance, etc. in accordance with current regulations and guidelines.

16. Any change in the composition of IEC will be intimated in writing to the Licensing Authority within 30 days.
4) **Responsible Person(s):** Director, Cancer Institute (WIA), IEC Members

5) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.

3) Good Clinical Practice Guidelines for clinical trials in India.

4) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose:** To appoint members for the institutional ethics committee, Cancer Institute (WIA)

2) **Scope:** Applicable to the institutional ethics committee, Cancer Institute (WIA)

3) **Procedure:**

1) Ethics committee should be multidisciplinary and multisectoral in composition with at least seven to fifteen members as per the Licensing Authority.

2) One of the members of the ethics committee who is from outside the institution would be appointed as Chairman. Member secretary can be from the same institution for operational convenience.

3) The ethics committee shall include one member whose primary area of interest or specialization is non-scientific and at least one member who is independent of the institution. IEC would be constituted without any gender bias.

4) The members representing medical scientist and clinician should have post graduate qualification and adequate experience in their respective fields.

**Terms of Reference:**

5) The appointment of an ethics committee member will be on voluntary service basis.

6) Chairman IEC may review the contribution of IEC members for continuation in the same capacity. The same is done with IEC Secretariat also.

7) During the term, the Director in consultation with IEC Chairman can replace any IEC member if the contribution is not adequate and/or there is long period of non-availability. He/she can reconstitute or redefine IEC Secretariat scope and functions.

8) Member will have the right to discontinue from membership of ethics committee after giving written notice, at least one month in advance.
9) Members should be aware of their roles and responsibilities in ethics committee as per current regulations and national ethical guidelines.

10) Each member is required to sign confidentiality agreement form regarding institutional ethics committee activities and declares conflict of interest before commencement of ethics committee meeting.

4) **Responsible Person(s):** Director, Cancer Institute (WIA), Chairman, IEC

5) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.

3) Good Clinical Practice Guidelines for Clinical Trials in India.

4) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Policy:** New and existing members of IEC would undergo required training on current regulations, guidelines, IEC policies and procedures every two years.

2) **Objective:** To set the processes in place for the IEC members to be trained on current regulations, guidelines, policies and procedures from time to time.

3) **Definitions:**
   
   i) **Training Record:** A record of training completed by the members of the IEC on provisions for clinical trials under Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945, National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants, Good Clinical Practice Guidelines for Clinical Trials in India.
   
   ii) **Curriculum Vitae (CV):** A CV is written, signed and dated to provide clear, comprehensive and concise evidence of education, qualifications, experience and training relevant to the ethics committee member role and responsibility.

4) **Procedure:**

   1) As per Appendix VIII of Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945, members of the IEC should be conversant with provisions for clinical trials under Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945, National Ethical Guidelines, Good Clinical Practice Guidelines for Clinical Trials in India to safeguard the rights, safety and wellbeing of all the clinical trial participants.

   2) The policy of IEC, Cancer Institute (WIA) is to see that the new and existing members of the IEC undergo required training every two years either in house or equivalent outside. The IEC members will be appraised of any amendments to the regulations and guidelines as appropriate.

   3) Cancer Institute (WIA) organizes the training program for the new and existing members of the IEC on the following,

   i) Provisions for Clinical Trials under Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945 (as amended from time to time)
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<td>Dr. R. Swaminathan</td>
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<td>Name</td>
<td>Chakradhara Reddy Padala</td>
<td>Name: Dr. R. Swaminathan</td>
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<td>Dr. V.I. Mathan</td>
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ii) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

iii) Good Clinical Practice Guidelines for Clinical Trials in India

iv) Other National & International regulations and Guidelines, as applicable.

v) IEC Policies and Standard Operating Procedures.

4) The training program will be organized by the Cancer Institute (WIA) either by external trainer or internal trainer or by a member of the IEC, as appropriate. The committee of Chairman of IEC, Member secretary of IEC and Head of institute will be the deciding authority for the training program for IEC Members.

5) All the IEC members are expected to familiarize themselves with policies and SOP’s especially those that are relevant to their current roles and responsibilities.

6) The IEC Secretariat will maintain a training record of every IEC member and place it for any audit.

7) The ethics committee training records should contain at least the following,

   i) Current CV of member signed and dated

   ii) Training completion certificate

   iii) Evidence of ethics committee policies and standard operating procedures training completion.

8) The IEC secretariat staff will have to undergo training on Schedule Y of Drugs & Cosmetics Act 1940 and Rules 1945 as amended from time to time, National Ethical Guidelines for Bio-Medical and Health Research Involving Human Participants, Good Clinical Practice guidelines for Clinical Trials in India and administration.

5) **Responsible Persons:** Director, Cancer Institute (WIA), Chairman & Member Secretary, IEC.
6) References:

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical Research Involving Human Participants.

3) Good Clinical Practice Guidelines for Clinical Trials in India.

4) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose:** To clarify on roles and responsibilities of the members of the ethics committee.

2) **Scope:** Applicable to the ethics committee, Cancer Institute (WIA).

3) **Procedure:**

   1) All the IEC members should be trained to be knowledgeable about the current
      
      a) Provisions for Clinical Trials under Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 (as amended from time to time).
      
      b) National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants.
      
      c) Good Clinical Practice Guidelines for Clinical Trials in India.
      
      d) Other applicable national and international regulations and guidelines.
      
      e) Policies and Standard Operating Procedures of the IEC.

   2) The basic responsibility of the members of the IEC is to safeguard the rights, safety and wellbeing of all research subjects. Special attention should be paid to the clinical trials that may include vulnerable groups as research participants.

   The rights and responsibilities of the research subjects includes

   **Rights:**
   
   (i) Right to information
   
   (ii) Access to medical records and reports
   
   (iii) Informed consent
   
   (iv) Second opinion
   
   (v) Confidentiality and privacy

   **Responsibilities:**
   
   (i) Compliance to study protocol requirements.

   3) All the IEC members should ensure that the proposed study protocol and/or other study documents adequately addresses the relevant ethical concerns and meets all applicable
regulatory requirements for clinical trials, specifically informed consent documents. Members must provide independent opinion on ethical aspects of research proposals.

4) Members disclose to the committee in writing, any interest they may have that could constitute a conflict of interest or otherwise bias their evaluation of research proposal.

5) All the members are responsible for competent and thorough review of initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received in an objective, timely and independent manner by attending meetings, participation in discussions and deliberations.

6) Ethics committee should review and approve the suitability of the investigator and trial site for adequate resources for each proposed clinical trial before issuance of approval letter.

7) The IEC members should ensure that research at Cancer Institute (WIA) is in compliance with current applicable national, international regulations and guidelines with high standards of quality and integrity.

8) All the members should review study monitoring reports, progress reports, final study reports, audit reports and SAE reports in timely manner.

9) In case of serious adverse event (SAE) of injury or death to the clinical trial subjects during the clinical trial, the ethics committee should analyze the SAE and forward its opinion on compensation to the Licensing Authority as per the procedures specified under Appendix XII of Schedule Y.

10) The IEC oversees critical functions of research conducted on human subjects that are scientific, ethical and regulatory. The designated members have the responsibility of overseeing the research function through regular site visits for monitoring and periodic audit through progress reports.

11) Periodic review of approved studies in the form of site visit for monitoring will be undertaken using GCP check-list (CDSCO). The criteria could involve subject accrual, reporting of SAE, protocol deviations and non-compliance issues.

12) Members must regularly update their knowledge about the ethical conduct of health
related research.

13) The IEC should ensure that it has sufficient resources (required space, infrastructure and manpower) to meet its operations. IEC does not handle any financial transactions in the form of receipts and payments. The institute will be responsible for meeting all costs if any, incurred through IEC operations. Member secretary, IEC, will serve as the liaison officer. Chairman should have memorandum of understanding (MOU) with head of the Institute for independent function of IEC.

14) Ethics committee should inform in writing to the Licensing Authority in case of any change in membership or the constitution of the ethics committee within 30 days.

15) If any member wishes to withdraw from the IEC membership, he/she should inform the Chairman of the ethics committee one month in advance to fulfill regulatory requirements like intimating the Licensing Authority and appointing new member as substitute.

16) The ethics committee should allow inspectors or officials authorized by the Central Drugs Standard Control Organization (CDSCO) / International Regulatory Authorities to enter premises to inspect any clinical trial record, data or documents related to clinical trials at the Cancer Institute (WIA) subject to applicable laws and guidelines.

17) Any important communication from the Licensing Authority to IEC on compliance issues/functions will be communicated to the Director, as appropriate.

18) Member specific roles and responsibilities are detailed in Annexure 5.1 of this SOP.

4) **Responsible Person(s):** All the members of the ethics committee.

5) **References:**
   1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.
   3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
   4) ICH - E6 (R2): Good Clinical Practice (GCP).
Annexure 5.1
Member Specific Roles and Responsibilities

1) Chairman/Vice Chairman (Optional):
   a) Conducting ethics committee meetings.
   b) Ensuring effective participation of all members.
   c) Ratify minutes of previous meetings.
   d) Seek conflict of interest declaration from members and ensure quorum and fair decision making.
   e) Handle performance evaluation of ethics committee members, ethics committee secretariat on an annual basis, complaints against researchers, ethics committee members and conflict of interest resolution.
   f) Scientific and ethical review of submitted documents for approval.

2) Member Secretary:
   a) Schedule ethics committee meeting; prepare the agenda and minutes of the meeting.
   b) Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for thorough review.
   c) Organize IEC documentation, communication and archiving.
   d) Ensure training of IEC members and IEC secretariat.
   e) Ensure IEC policies and SOPs are updated as and when required.
   f) Ensure implementation of IEC policies and SOPs.
   g) Prepare for and respond to audits and inspections.
   h) Ensure completeness of documents and timely inclusion in agenda for IEC review.
   i) Initial assessment of need for expedited review/exemption from review or full review, for concurrence of IEC thereafter.
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j) Obtaining prior scientific review, invite independent consultant, patient or community representative.

k) Ensure quorum during meeting and record discussions and decisions.

i) Scientific and ethical review of submitted documents for approval.

3) Medical Scientist:

   a) Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, Protocol deviation, study progress and study completion report.

4) Clinician:

   a) Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics, continuing review process, SAE, protocol violation, protocol deviation, study progress and study completion report.

   b) Review of medical care, facility and appropriateness of principal investigator/change of investigator, provision for medical care management and compensation.

   c) Thorough review of protocol, investigators brochure and all other protocol details and submitted documents.

5) Legal Expert/s

   a) Ethical review of proposal, review of (i) Informed consent document along with translations, (ii) Memorandum of Understanding (MOU), Clinical Trial Agreement (CTA), Regulatory approval, insurance document, other site approvals, investigator undertaking, other protocol specific permissions, Institutional Committee for Stem Cell Research approval, Health Ministry Screening Committee (HMSC) approval for international collaboration, compliance with regulations and guidelines.

   b) Interpret and inform ethics committee members about new regulations and guidelines, if any.
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6) Social Scientist / Philosopher / Ethicist / Theologian

a) Ethical review of proposal, review of informed consent document along with translations.

b) Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any.

c) Serve as patient / participant / societal / community representative and bring in ethical and societal concerns.

d) Assess on societal aspects, if any.

e) Scientific and ethical review of submitted documents for approval.

7) Lay Person:

a) Ethical review of proposal, review of informed consent document along with translations

b) Evaluate benefits and risks from the participant’s perspectives and opine whether benefits justify risks.

c) Serve as patient / participant / societal / community representative and bring in ethical and societal concerns.

d) Assess on societal aspects if any.

e) Essential part of Schedule Y Quorum.
1) **Purpose**: To conduct the institutional ethics committee meetings.

2) **Scope**: Scheduling and procedures for the IEC meeting, Cancer Institute (WIA)

3) **Procedure**:

   1) The member secretary in consultation with the chairman and members of the IEC will schedule the ethics committee meeting at the Cancer Institute (WIA) once in every 3-4 months. This is keeping in mind the Scientific Advisory Committee (SAC) & Data and Safety Monitoring Board (DSMB) meetings that aid in IEC review of scientific and ethical aspects.

   2) The communication on the scheduled ethics committee meeting will be sent to the principal investigators, researchers and HODs 3-4 week, in advance.

   3) The last date for submission of the study protocol documents to the ethics committee for review is at least two weeks before the scheduled IEC meeting.

   4) The ethics committee secretariat staff will verify all the submitted study protocol documents for completeness and co-ordinates with the investigator until the documentation is completed. The Annexure 7.1 in SOP 07 lists the set of documents required for submission.

   5) The ethics committee reviews only the final and completed versions of study protocol documents and does not review draft and incomplete version of study protocol documents.

   6) Scientific review will be completed before the ethical review. Scientific advisory committee approval is generally required for the review of the new proposals by IEC. However in exceptional circumstances like retrospective studies, ongoing studies that require IEC approval may be taken up for direct IEC review.

   7) The member secretary/ethics committee secretariat forwards the soft copy of new study protocol documents/protocol amendments/others to all the IEC members ten days in advance for thorough review.
Review of study protocols will be done in compliance with the current regulations and guidelines, as applicable.

8) Meeting agenda will be prepared and sent to the members during the week of the meeting. If any additions (after the circulation of the agenda to the members) at the discretion of chairman and member secretary, new items can be added under additional agenda section. The following are the standard agenda items,

i. Opening remarks

ii. Conflict of interest declarations

iii. Review of previous minutes of the meeting

iv. Review of action taken reports

v. Review of DSMB minutes

vi. Review of new submissions

vii. Review of re-submissions

viii. Review of protocol amendments

ix. Review of notifications/others

x. Review of regulatory and administrative Items

xi. Additional agenda items, if any.

xii. Closing remarks and vote of thanks

9) Study protocol title and principal investigators names should be reflected in the agenda under each new protocol submission, re-submission, and protocol amendment, other sections as appropriate.

10) Principal investigators and the team will be invited to the ethics committee meeting
to present the proposed study protocol/protocol amendment to the ethics committee.

11) The quorum of the IEC during the meeting should be at least 5 members with following representation.

   i. Basic Medical Scientist
   ii. Clinician
   iii. Legal Expert
   iv. Social Scientist
   v. Lay person

12) The quorum for reviewing the regulatory and global clinical trials should be in accordance with current CDSCO requirements.

13) The chairman and member secretary could have dual roles in the ethics committee. They could fulfill a role based on their qualifications (such as that of clinician, legal expert, basic medical scientist, social scientist, lay person) in addition to taking role of chairman and member secretary.

14) No decision is valid without fulfillment of the quorum. This is applicable even for proposals approved under “Expedited Review Category”.

15) If the quorum is not met on the day of the ethics committee meeting, the proposals can be discussed, whereas the decision on the approval of research proposals can be taken only during the next ethics committee meeting when the above quorum will be met.

16) If the ethics committee is unable to review an agenda item due to time constraints or quorum issues during the convened meeting, the agenda item will be rescheduled to subsequent meeting.

17) Independent subject experts may be invited to the meetings as per demands of the proposed study protocol for their opinion, but they will not play any role on decision making.
18) Attendance at the ethics committee meeting is limited to the ethics committee members, secretariat staff and invited principal investigator/study representative/study team.

19) The member secretary (assisted by the secretariat) should record the discussions and prepare the minutes of the meeting which should be circulated to all the members for comments before final approval by the chairman/Vice-chairman/designated member of committee.

20) Minutes of the ethics committee meetings, all the proceedings and deliberations need to be documented and signed & dated by the chairman and member secretary.

4) **Responsible Person:** Member secretary, Institutional Ethics Committee

5) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.


3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.

4) ICH - E6 (R2): Good Clinical Practice (GCP).
1. **Purpose**: Submission of research proposals/others to the ethics committee for review.

2. **Scope**: New proposals, protocol amendments, protocol deviations, change of principal investigator, non-compliance, complaints and other communications.

3. **Procedure**:
   
   1) IEC review of study proposals are limited to the ones conducted at the institute with principal investigators/co-investigators, among the faculty/researchers of the institute.

   2) All proposals should be submitted with a covering letter to the chairman/member secretary of IEC duly signed by the principal investigator enclosing all required documents, which requires the ethics committee review (Annexure 7.1). This is applicable for all protocol amendments thereafter. Protocol amendments should be assigned with version number in sequential order as appropriate with date.

   3) One hard copy and a soft copy are required to be submitted to the IEC Secretariat two weeks (14 days) in advance of the scheduled IEC meeting.

   4) Study proposal for review should be complete in usual standard format including study background, review of literature, objectives, material and methods. The additional documentation required in the proposal is given in detail in current National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants 2017 (Reference Box 4.4 (b) page No.34).

   5) Study Annual Progress Reports: Notification of study annual progress report to the IEC should contain the following details:

   a. Date of IEC approval of the study at site
   b. Date of site initiation visit
   c. No. of subjects screened
   d. No. of subjects randomized
   e. No. of subjects completed treatment
   f. No. of subjects lost to follow up
   g. No. of subjects drop out
h. No. of adverse events
i. No. of serious adverse events
j. No. of protocol violation and protocol deviation from site initiation visit till date

6) Plans for dissemination of the results of the study are welcome.

7) Acknowledgement of receipt of study proposals/application/notification will be issued by member secretary/IEC secretariat.

8) Every new proposal application will be allotted a reference number by the IEC secretariat to be used by the applicant for all future reference and correspondence.

9) Principal investigators or their authorized nominee involved in conduct of the study are required to present oral presentation to the IEC, as applicable.

10) IEC secretariat initiates the review process of submitted documents through the member secretary.

11) Notifications of change of investigator, protocol violation, protocol deviations, non-compliance, complaints by past, current clinical trial participants/others should be addressed in writing to the Chairman/Member Secretary with supporting documents, if any.

12) An acknowledgement will be issued by the IEC secretariat for all the notifications. Action to be taken will involve receiving inputs from the Data and Safety Monitoring Board (DSMB), principal investigators and the designated IEC sub-committee, as appropriate.

4. **Responsible Person(s):** Principal Investigator, Chairman, Member Secretary, Ethics Committee
5. References:

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.


3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.

4) ICH - E6 (R2): Good Clinical Practice (GCP).
Annexure 7.1

Documents required to be submitted for the IEC review:

1) Cover letter to the Chairman/Member Secretary

2) Type of review requested

3) Study Protocol / Protocol Amendment / other documents

4) The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)

5) Case record form/questionnaire

6) Recruitment procedures: advertisement, notices (if applicable)

7) Patient instruction card, diary, etc. (if applicable)

8) Investigator’s brochure (as applicable for drug/biologicals/device trials)

9) Details of funding agency/sponsor and fund allocation (if applicable)

10) Brief curriculum vitae of all the study researchers

11) A statement on Conflict of Interest (COI), if any

12) Good Clinical Practice (GCP) training completion certificate (preferably within 5 years) of investigators and study team (clinical trials)

13) Any other research ethics/other training completion evidence (Recommended for clinical trials personnel)

14) List of ongoing research studies undertaken by the principal investigator.
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15) Investigators undertaking as per Appendix VII of Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945.

16) Regulatory permissions (as applicable)

17) Relevant administrative approvals for international studies (such as Health Ministry Screening Committee, ICMR approval etc.)

18) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)

19) Memorandum of Understanding (MoU) in case of studies involving collaboration with other institutions (if applicable)

20) Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)

21) Clinical Trials Registry-India (CTRI) registration (if applicable)

22) Insurance policy for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

23) Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)

24) Any additional document(s), (such as other EC clearances for multicentric studies)
1) **Purpose:** Ethical review of the research proposals submitted by the investigators to IEC.

2) **Scope:** Compliance to regulations, ethical guidelines, scientific and overall procedural aspects

3) **Procedure:**

1) The sponsor and/or investigator should seek the opinion of the IEC regarding suitability of the study protocol including methods and documents to be used in recruitment of subjects and obtaining their informed consent including adequacy of information being provided to the subjects in the informed consent document (Annexure 8.1).

2) The basic responsibility of the IEC is to ensure competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity.

3) It is the responsibility of the IEC to safeguard the rights, safety and well being of all study subjects.

4) Study subject rights and responsibilities are as follows:

   **Rights:**
   a) Right to information
   b) Access to medical records and reports
   c) Informed consent
   d) Second opinion
   e) Confidentiality and privacy

   **Responsibilities:**
   a) Compliance to study protocol requirements.

5) All members are required to evaluate every protocol submitted on ethical issues, scientific and technical aspects of the proposed research. This applies to any protocol amendments also. Special emphasis will be laid on the basis for amendment and the possible impact on the overall study elements from objects to patient safety.
6) All members should evaluate the possible risks to the study participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

7) Elements of review includes the following items:

   a) Scientific design and conduct of the study

   b) Approval of Scientific Advisory Committee (SAC) of the Cancer Institute (WIA), as applicable.

   c) Examination of predictable risks /harm

   d) Examination of potential benefits to the study subjects and community at large.

   e) Procedure for selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues like advertisement details, as applicable.

   f) Management of research related injuries, adverse events etc.

   g) Compensation provisions

   h) Justification for placebo in control arm, if any.

   i) Availability of investigational products after the study, if applicable

   j) Patient information sheet and informed consent form in local languages

   k) Protection of privacy and confidentiality

   l) Involvement of the community, wherever necessary

   m) Plans for data analysis and reporting

   n) Compliance to all regulatory requirements and applicable guidelines

   o) Qualification, experience and Good Clinical practice (GCP) training completion of principal investigator and research team

   p) Resources, facilities and infrastructure at site for the proposed clinical trial/study

   q) Criteria for withdrawal of patients, suspending or terminating the study

   r) Procedure for change in principal investigator, research team, etc., if any.

8) Informed consent form should be verified whether it is in accordance with Appendix V of Schedule Y of Drugs & Cosmetics Act 1945 & Rules 1945 for essential elements
and format (Please see Annexure 8.1 of this SOP).

9) For all global clinical trials/clinical trials of new drugs/new chemical entity, the Drugs Controller General of India approval/No objection certificate is mandatory.

10) As per Drugs Controller General Order dated 05.09.2014 all the global clinical trials (GCTs)/New Drugs / New Chemical Entity (NCEs) should be evaluated having regard to three parameters cited below and record the same in the minutes of the meeting.

i) Assessment of risk versus benefit to the patients

ii) Innovation vis-à-vis existing therapeutic option and

iii) Unmet medical need in the country

11) For clinical trials of new drugs wherever audio visual recording of informed consent process is mandatory the reviewers/investigators should follow the appropriate guidance documents for compliance.

12) For clinical trials conducted in pediatric population (Vulnerable Group), the IEC should include members who are knowledgeable about pediatric, ethical, clinical and psychosocial issues.

13) All the contents of the proposed protocol, for conducting clinical trials (as specified in Appendix X of the Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 should be carefully reviewed, as appropriate. (Please see Annexure 8.2 of this SOP)

14) Appropriate regulations and guidelines should be followed when reviewing, the bio-similar, vaccine, stem cell, surgical procedure, medical device, diagnostic agents based research proposals and studies in special population. This will include health, safety and rights of the donor, wherever applicable, informed consent, etc. Expert opinion on study proposals will be obtained if necessary.

15) Review of notifications like protocol violation, protocol deviation, non-compliance and complaints by current/past research participants/stake holders requiring urgent attention will be done by a sub-committee of IEC members (Chairman, Member Secretary and one other IEC member) and/or other required consultants. All items will be included in the agenda and tabled in IEC meeting for discussion and decision.
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16) In case where a conflict of interest arises that may damage the scientific integrity of a project or cause harm to research participants, the members would take decision carefully after a thorough review. In case of decision to approve, appropriate advice must be given to the investigators (to declare such conflict of interest to the IEC and future publication) and verify if the participants are informed of the sponsorship of the research as applicable.

17) Members are encouraged to refer to all the prevailing rules, regulations and guidelines available in the secretariat as required.

4) **Responsible Person(s):** All the members of the ethics committee

5) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.
3) National Ethical Guidelines for Bio-medical and Health Research Involving Children issued by ICMR
5) National Health Policy 2017
6) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
7) ICH - E6 (R2): Good Clinical Practice (GCP).
8) Handbook for Applicants & Reviewers of Clinical Trials of New Drugs in India.
Annexure 8.1

Checklist for Review of Informed Consent Documents (As per Appendix V of Schedule Y of Drugs & Cosmetics Act)

1. Essential elements:
   1. Statement that study involves research and explanation of the purpose of the research
   2. Expected duration of the subjects participation
   3. Description of the procedures to be followed, including all invasive procedures and
   4. Description of reasonably foreseeable risks or discomforts to the subject
   5. Description of any benefits to the subject or other’s reasonably expected from research
      if no benefit is expected subject should be made aware of this.
   6. Disclosure of specific appropriate alternative procedures or therapies available to the
      subject.
   7. Statement describing the extent to which confidentiality of records identifying the
      subjects will be maintained and who will have access to subjects medical records
   8. Trial treatment schedules and the probability of random assignment to each treatment
      (for randomized trials)
   9. Compensation and/or treatment(s) available to the subject in the event of a trial related
      injury
   10. An explanation about whom to contact for trial related injuries, rights of subjects and
       in the event of any injury
   11. The anticipated pro-rated payment, if any, to the subject for participating in the trial
12. Subjects responsibilities on participating in the study

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

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

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

16. Any other pertinent information.

1.1 Additional elements which may be required

1. Statement of foreseeable circumstances under which the subject’s participation may be terminated by the investigator without the subjects consent.

2. Additional costs to the subject that may result from participation in the study

3. The consequence of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by subject.

4. Statement that the subject or subjects representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subjects willingness to continue participation will be provided

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

6. Approximate number of subjects enrolled in the study.
2. **Format of Informed Consent Form For Subjects Participating in a Clinical Trial**

Informed consent form to participate in a clinical trial.

- **Study Title:**
- **Study Number:**
- **Subject Initials:**
- **Date of birth/Age:**
- **Address of the subject**
- **Qualification:**
- **Occupation:**
- **Annual Income of the subject:**
- **Name and address of the nominee(s) and his relation to the subject:**
  (for the purpose of compensation in case of trial related death)

Please initial box
(Subject)

(i) I confirm that I have read and understood the information sheet dated
    For the above study and have had the opportunity to ask questions

(ii) I understand that my participation in the study is voluntary and that I am free to
    withdraw at any time, without giving any reason, without my medical care or
    legal rights being affected.

(iii) I understand that the sponsor of the clinical trial, others working on the sponsor’s
    behalf, the ethics committee and the regulatory authorities will not need my
    permission to look at my health records both in respect of the current study and
    any further research that may conducted in relation to it, even if I withdraw from
    trial. I agree to this access. However, I understand that my identity will not be
    revealed in any information released to third parties or published.
(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)  

(v) I agree to take part in the above study

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

---------------------------------------------
Date: ----/----/-----
Signatory Name: -------------------------------------
Signature of the Investigator: -------------------
Date: ------/------/-----
Name of the Investigator: ----------------------
Signature of the witness: ----------------------
Date: ------/------/-----
Name of the witness: ----------------------

[Copy of the patient information sheet and duly signed informed consent shall be handed over to the subject or his / her attendant.]
Annexure 8.2

Contents required for the proposed protocol for conducting clinical trials (As per Appendix X of Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945)

1. Title Page
   a) Full title of the clinical study
   b) Protocol / study number, and protocol version number and date
   c) The IND name / number of the investigational drug
   d) Complete name and address of the sponsor and contract research organization if any, along with authorized individuals
   e) List of investigators who are conducting the study, their respective institutional affiliations and site locations
   f) Name of clinical laboratories and other departments and/or facilities participating in the study.

2. Table of contents
   A complete of table of contents including a list of all appendices

1. Background
   a) Preclinical experience
   b) Clinical experience

Previous clinical work with new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.
2. Study Rationale:
This section should describe a brief summary of background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.

3. Study objectives: (Primary as well secondary) and their logical relation to the study design

4. Study design:
   a) Overview of study design: Including a description of the type of study (i.e., double blind, multicenter, placebo-controlled, etc.) a detail of the specific treatment groups and number of study subjects in each groups and investigative site, subject number assignment, and the type of, sequence and duration of study periods.

   b) Flow chart of the study

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

   d) Discussion of study design: The discussion details the rationale for the design chosen for this study and methods used (for equitable selection of subjects).

5. Study Population: The number of subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the subject (to ensure equitable selection of subjects as per national guidelines).

   Population required is also mentioned.

6. Subject eligibility.
   a) Inclusion criteria
   b) Exclusion Criteria

7. Study assessments – Plan, procedures and methods to be described in detail.

8. Study conduct stating the types of study activities that would be included in this section would be: Medical History, type of physical examination, blood or urine
testing, electrocardiogram (ECG), diagnostic testing such pulmonary function tests, symptom measurement, dispensation and retrieval of medication, subject cohort assignment, adverse event review etc.

Each visit should be described separately as visit 1, visit 2 etc.

9. Discontinued subjects: Describes the circumstances for subject withdrawal, dropouts or other reasons for discontinuation of subjects. State how drop outs would be managed and if they would be replaced.

10. Describe the method of handling of protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

11. Describe how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol.

12. Study treatment:

a) Dosing schedule (dose, frequency and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency and duration and duration of concomitant treatment should be stated.

b) Study drug supplies and administration: A statement about who is going to provide the study medication and that that investigational drug formulation has been manufactured following all regulations details of product stability, storage requirements and dispensing requirements should be provided.

c) Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.

d) Possible drug interactions

e) Concomitant therapy: the drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a subject is not allowed to use during the parts of or the entire study. If any
washout periods for prohibited medication are needed prior to enrollment, these should be described here.

f) Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and/or the subject.

g) Unbinding procedures: If the study is blinded, the circumstances in which unbinding may be done and the mechanism to be used for unbinding should be given.

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

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

15. Study Monitoring and Supervision: A description of study monitoring policies and procedures should be provided along with proposed frequency of site monitoring visits and who is expected to perform monitoring.

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

Investigator study files, including what needs to be stored following study completion should be described.
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16. Investigational Product Management:

a) Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study)

b) The precise dosing required during the study

c) Method of packaging, labeling and blinding of study substances

d) Method of assigning treatments to subjects and the subject identification code numbering system.

e) Storage conditions for study substances

f) Investigational product accountability: Describe instructions for the receipt, storage, dispensation and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed and returned/destroyed.

g) Describe policy and procedures for handling unused investigational products

17. Data Analysis:

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

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

Describe statistical considerations for pharmacokinetic analysis, if applicable.
18. Undertaking by the investigator (As per Appendix VII of Schedule Y)

19. Appendices: Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.) CRF and other data collection forms: a summary of relevant pre-clinical safety information and any other documents referenced in clinical protocol.
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1) **Purpose:** Ethical review of the research proposals submitted by the investigators which involves vulnerable population.

2) **Scope:** Research involving children, vulnerable population - Current regulations, ethical guideline, scientific aspects and overall procedures aspects.

3) **Procedure:**

1) The IEC should exercise particular care to protect the rights, safety and wellbeing of all vulnerable subjects participating in the study e.g. members of a group with hierarchical structure (e.g. Prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or others incapable of personally giving informed consent.

2) Vulnerable research participants are individuals whose willingness to volunteer in a research trial may be duly influenced by the expectation (whether justified or not), benefits associated with participation, retaliatory response from higher authority in case of refusal to participate and whose consent may not be valid for various reasons. They include infants, children and adolescents, pregnant and lactating women, students and employees, mentally challenged patients, critically ill patients.

3) Special emphasis must be laid on the need of the clinical trial involving vulnerable population.

4) All members should evaluate the possible risks (risk categorization, determinants of risk, pain, distress elements, etc.) to the study participants under this category with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue. This applies to any protocol amendments also. Special emphasis will be laid on the basis for amendment and the possible impact on the overall study elements from objects to patient safety.

5) Effort 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 genetics should not lead to racial or social inequalities

b) Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

c) Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.

d) Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, and service personnel etc. who have reduced autonomy as research subjects.

6) Vulnerable group can become participants only if the study is designed to protect or advance the health of this population and for which the non-vulnerable group would not be suitable participants

7) (a) In case of trials involving children, oral assent of the child should be obtained from the age of seven to eleven years in the presence of parent or legal guardian; written consent of the child should be obtained from age 12 to 18 years unless there is no medically accepted alternative to the therapy (provided consent has been obtained from parents/guardian) (Reference: National Ethical guidelines for children (3))

(b) Assent is defined as a child’s affirmative agreement to participate in the research. According to developmental level, assent form should be chosen. Waiver of assent may be granted in specific circumstances (Reference: National Ethical guidelines for children (3))

8) Rights and welfare of people who are unable to give informed consent must be protected. Informed consent should be obtained from legally authorized representatives in the presence of impartial witness with adequate explanation of risks and benefits.

9) Expert opinion of additional members would be obtained for review, if necessary

10) The IEC should ensure that appropriate decisions are made and documented as required in the minutes of the meeting.
4) **Responsible Person(s):** Chairman, Member Secretary and all the members of the ethics committee

5) **References:**

1. Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time
2. National Ethical Guidelines for Bio-medical and Health Research involving Human Participants
3. National Ethical Guidelines for Bio-medical Research involving Children
4. Good Clinical Practice Guidelines for Clinical Trials in India
5. ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose:** To review the Serious Adverse Events (SAE) of all clinical trials (Academic and Industry Sponsored).

2) **Scope:** Compliance to regulations, ethical guidelines, Data and Safety Management Board (DSMB) involvement.

3) **Procedure:**

   1) A serious adverse event is an untoward medical occurrence during the clinical trial that is associated with death, in patient hospitalization (in case the study was being conducted on outpatient) prolongation of hospitalization (in case of study being conducted on in patient) persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening.

   2) The principal investigators are required to prepare the serious adverse event report in accordance with the Appendix XI of Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945.

   3) The principal investigator of industry sponsored clinical trials shall report all serious adverse events to the (i) Licensing Authority as defined under clause (b) of rule 21, (ii) the sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial and (iii) the ethics committee that accorded approval to the protocol of new drugs, within twenty four hours of their occurrence as per Appendix XI of Schedule Y of Drugs and Cosmetics Rules 1945.

   4) In case the principal investigator fails to report any serious adverse event within the above stipulated period, he or she shall have to furnish the reason for delay to the satisfaction of the Licensing Authority along with report of the serious adverse event.

   5) The Licensing Authority shall determine the cause of injury or death as per the procedures prescribed under Appendix XII of Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945 and pass orders as deemed necessary.

   6) Principal investigator irrespective of whether industry sponsored or academic clinical trial should report all serious adverse events (SAE) occurring to the clinical trial subjects to the IEC within 24 hours.
7) The serious adverse event report should be submitted to the ethics committee, Cancer Institute (WIA) with a covering letter addressed to the chairman/member secretary.

8) The SAE notification report to the ethics committee, Cancer Institute (WIA) should have
   i. Covering letter with principal investigator/authorized signatory signature and date
   ii. Duly filled SAE form as per Appendix XI of Schedule Y
   iii. Relevant supporting documents (copy of investigations, SAE summary report etc.)

9) SAE acknowledgement copy signed by member secretary/IEC secretariat will be issued.

10) In case of injury or death to the clinical trials subject the principal investigator should submit causality assessment with reasoning for relatedness/un-relatedness to study drug or intervention.

11) The member secretary, IEC will initially review all the submitted SAE notifications and initiates further action for the decision.

12) The broad parameters for decision on compensation, are as below:
   a) Adverse effect of investigational product(s)
   b) Any clinical trial procedures involved in the study.
   c) Violation of approved study protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator
   d) Failure of investigational product to provide intended therapeutic effect
   e) Use of placebo in a placebo-controlled trial.
   f) Adverse effects due to concomitant medication excluding standard of care, necessitated as part of approved protocol.
g) Injury to the child in utero because of the participation of parent in clinical trial.

[Ref: Schedule Y Rule 122 DAB item (5)]

13) (a) In any industry sponsored clinical trial, if any SAE-Injury or death occurs, the SAE report is forwarded to the following 4 persons for review under the expedited review category,

(i) IEC Chairman
(ii) Any designated IEC Member
(iii)Member Secretary, IEC
(iv)Chairman, DSMB

(b) After thorough review, the final report on casualty and associated compensation, if any, are submitted to the licensing authority within prescribed timelines i.e. within 30 days (Ref: Appendix XII of Schedule Y of Drugs & Cosmetics Act 1940 and Rules 1945)

(c) For academic clinical trials, the same procedure for review of SAEs is followed. However all SAEs will be discussed in DSMB meeting and recommendations for compensation, if any, are forwarded to IEC for decision.

(d) The sponsor/base institution/investigator is responsible for instituting mechanisms for the compensation for the research related injury.

(e) The decision of IEC on compensation will prevail over sponsor’s informed consent documents.

14) In case of SAE of academic clinical trials, the same procedure outlined in item 13 above will be followed, excepting reporting to the Licensing Authority.

15) The IEC will refer Drugs & Cosmetics Act 1940 & Rules 1945 as amended from time to time for current guidance on formulae for compensation for the SAE of Injury and Death in clinical trials.
16) As a policy, all the SAE's notified to the IEC will be reviewed and discussed in the Data and Safety Monitoring Board (DSMB) meeting of the Cancer Institute (WIA).

17) The full IEC will review the DSMB reports and all the industry sponsored SAE notifications during the scheduled ethics committee meetings.

18) The ethics committee can visit the study site as appropriate on SAE Notification for studying the protocol and good clinical practice compliance verification.

19) All ethical review points along with Data and Safety Monitoring Board minutes of the meeting recommendation will be documented in minutes of the meeting of IEC.

4) Responsible Person(s): All the ethics committee members

5) References:

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time
2) National Ethical Guidelines for Bio-medical and Health Research involving Human Participants 2017
3) National Ethical Guidelines for Bio-medical Research involving Children
4) Guidance Document on SAE from CDSCO.
5) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
6) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Policy:** Disclosure of conflict of interest of any nature by every IEC Member before the IEC meetings is mandatory.

2) **Purpose:** To provide guidance on voluntary disclosure of conflict of interest (COI) by IEC members in agreement with underlying policy.

3) **Definition:**

   **Conflict of Interest (COI):** Conflict of interest is a set of conditions where professional judgment concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political).

4) **Procedure:**

   1) As per Appendix VIII of Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945, under requirements and guidelines for registration of the ethics committee, point number 2(h) states that “there should be no conflict of interest”.

   2) The policy of IEC is disclosure of conflict of interest of any nature by every IEC member in compliance with Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945 & National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017.

   3) The ethics committee, Cancer Institute (WIA) strongly recommends its members to voluntarily disclose and eradicate the conflict of interest of all kinds.

   4) The IEC Secretariat will provide conflict of interest disclosure forms to the members along with meeting agenda before the start of the scheduled ethics committee meeting.

   5) All the ethics committee members should submit signed and dated conflict of interest disclosure forms to the chairman, ethics committee before the commencement of every IEC meeting.

   6) The chairman, ethics committee, Cancer Institute (WIA) resolves the conflict of interest matters in the ethics committee.
7) Chairman and member secretary of the ethics committee will review the conflict of interest disclosure forms and record in the minutes of the meeting.

8) Members having conflict of interest would be withdrawn from the decision making process of the ethics committee meeting, specific to conflict of interest disclosure.

9) However, member with conflict of interest can provide review comments to the ethics committee, but will not be part of decision making process.

5) **Responsible Person(s):** Chairman, IEC

6) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research involving Human Participants

3) Good Clinical Practice Guidelines for Clinical Trials in India

4) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose:** Expedited review and subsequent approval of a research proposal.

2) **Scope:** Need based review based on study requirements and risk category.

3) **Procedure:**

   1) IEC will receive and consider proposals under expedited review for studies involving,
      (Annexure 12.1)
      
      i) No or minimum risk to the trial participants
      ii) Re-examination of a proposal already examined by IEC
      iii) Study of minor nature like examination of case records
      iv) Study proposals that are similar to the one which IEC had already given
          approvals earlier
      v) An urgent proposal of national interest having minimum risk
      vi) Ongoing studies requiring IEC approval as part of subsequent revised
          guidelines.

   2) All other proposals which do not comply with above criteria will be reviewed in the
      regular IEC meeting.

   3) All expedited review proposals will be reviewed by sub-committee of three members.
      Chairman, member secretary and one member as designated by the chairman will
      normally be the sub-committee. All the three members should be present for the
      meeting (face-to-face or tele/video conference) and should declare no conflict of
      interest.

   4) The sub-committee should review all the documents as per governing regulations
      under expedited review.

   5) Decision taken by the sub-committee on expedited approval will be placed in the main
      ethics committee meeting at the next regular ethics committee meeting for the final
      decision.

   6) The final decision by the main IEC review will be binding and will overrule any earlier
      decision by the sub-committee.
4) **Responsible Person(s):** Chairman, Member Secretary and all the members

5) **References:**

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research involving Human Participants

3) Good Clinical Practice Guidelines for Clinical Trials in India

4) ICH - E6 (R2): Good Clinical Practice (GCP).
Annexure 12.1

Proposals that pose no more than minimal risk may undergo expedited review.

For example:

a. Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and leftover clinical samples;

b. Research involving clinical documentation materials that are non-identifiable (data, documents, records);

c. Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in Researcher(s);

d. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

e. Minor deviations from originally approved research causing no risk or minimal risk;

f. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee

In all sponsored studies SAE’s will be reviewed under expedited review.

h. For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

i. Research during emergencies and disasters.
### Institutional Ethics Committee Cancer Institute (WIA)

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<tr>
<th>SOP No</th>
<th>CI/IEC/13</th>
<th>Effective Date</th>
<th>SOP Title: Procedure for Decision Making on Research Proposals/others</th>
<th>Version No</th>
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<tr>
<td>Name</td>
<td>Chakradhara Reddy Padala</td>
<td>Reviewed By Dr. R. Swaminathan</td>
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<td>Approved by Dr. V.I. Mathan</td>
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<tr>
<td>Designation</td>
<td>Clinical Research Associate</td>
<td>Designation Member Secretary</td>
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<td>Designation Chairman</td>
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1) **Purpose**: To make a decision on the submitted documents for ethical review and their documentation.

2) **Scope**: Research proposals, protocol amendments, notifications, change of principal investigator, SAEs, annual progress reports, protocol violations, protocol deviations, non-compliance, complaints and minutes of the meeting documentation.

3) **Procedure**:

1) All new research proposals, re-submissions, amended protocols, notifications on change of investigator, SAEs, progress reports as per the meeting agenda will be forwarded to the members for review before the scheduled ethics committee meeting.

2) Others if any received after the last date for the receipt will be added under the additional agenda of IEC meeting.

3) Members having conflict of interest will indicate the same to the chairman by signing conflict interest declaration form prior to the start of the IEC meeting.

4) Member with any conflict of interest of one or more of study documents will not participate in the decision making process of respective proposals, which will all be recorded in the minutes of the meeting.

5) Principal investigators or their authorized nominee involved in conduct of the study are required to submit an oral presentation to the IEC as applicable.

6) Every decision on research proposals/protocol amendments will be taken after sufficient time for the review and discussion, in the absence of the research team (i.e. Principal investigators) from the meeting.

7) Decisions will be taken in compliance with current national regulations, guidelines and Good Clinical Practice (GCP) Guidelines, as applicable.

8) Decision on research proposals involving global clinical trials/new drug/new chemical entity clinical trials should be taken only at IEC meetings where a quorum (As per Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945) is complete at least five members with the following representations.
9) Only IEC members should make the decision. The expert consultants, if any will only offer their opinion.

10) IEC decision may be to approve, reject or revise the proposals/protocol amendments. Specific suggestions for modifications and reasons for rejection should be given.

11) IEC decision will be taken through consensus. In the event of dissenting opinion voting will be taken.

12) All IEC members present will vote for or against approval to be granted. The decision will be taken based on majority. In case of deadlock, decision of the chairman is binding.

13) As per Drugs Controller General Order dated 05.09.2014 all the Global clinical trials (GCTs)/New Drugs/New Chemical Entity (NCEs) should be evaluated having regard to three parameters cited below and record the same in the minutes

   i) Assessment of risk versus benefit to the patients
   ii) Innovation vis-à-vis existing therapeutic option and
   iii) Unmet medical need in the country

14) The decision of the IEC will be communicated to the applicant in writing with review comments, if any and the same documented in the minutes. This includes research proposals, protocol amendments, non-compliance, protocol violations, protocol deviations and complaints from participant/stakeholders.

15) Approvals generally should be given for the duration of the study and specified in the approval letter. This applies to protocol amendments with specific mention of modified
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version number assigned. However, this will be subject to prior review of progress reports.

16) In case of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified. The same should be documented in the respective minutes of the meeting.

17) All review comments of initial review should be documented in the minutes of the meeting. Rejection of proposal/protocol amendment will be supported by clearly stated reasons and should be documented in the minutes.

18) The study proposals/protocol amendments incorporating the suggestions and addressing the reservations expressed by earlier IEC review may be reviewed by a sub-committee constituting at least 3 members (Chairman, Member secretary and a member nominated by chairman) in an expedited manner, as required.

19) There is no cap on the number of studies to be undertaken by an investigator. The IEC will examine the risks and complexity involved in the clinical trials being conducted/proposed and will decide on how many trials an investigator can undertake subject to adequate resources, from time to time.

20) Serious Adverse Event (SAE) notification of Injury and death requires causality assessment by the IEC as per Appendix XII of Schedule Y of Drugs & Cosmetics Act 1940 & Rules 1945 and the IEC should send its opinion on compensation within 30 days to the Licensing Authority.

21) IEC is responsible for overseeing the research activities at site, particularly for the conduct of clinical trials for all the approved research studies besides examining progress reports.

22) Site monitoring: The IEC will monitor the approved study at appropriate interval until completion of research to check for compliance to the approved protocol, applicable regulations, guidelines and standards.

The monitoring of site can be routine or for cause as per applicable regulations, guidelines and conditions as decided by the IEC. The sub-committee of three members
will monitor the site. Examples for for-cause monitoring are as follows,

a) High number of protocol violations/deviations  
b) Large number of proposals carried out at the study site/by the same investigator  
c) Large number of SAE reports  
d) High recruitment rate  
e) Non-compliance to IEC directions  
f) Misconduct by the researcher  
g) Complaints received from the study participant.  
h) Any other cause as decided by the IEC.

23) Minutes of the meeting (MOM) of IEC:

The deliberations in IEC meeting will be documented in the form of minutes of the meeting (MOM) as required. The essential elements of the minutes documentation are:

(a) Member secretary prepares the first draft of the minutes summarizing the key points of the deliberations after seeking inputs from other IEC members and incorporating them. 
(b) List of members/invitees attending the IEC meeting 
(c) Agenda as appendix
(d) All agenda items will be addressed in detail one by one under new proposal, re-submissions, protocol amendments, expedited review, notifications, SAEs, protocol violation, protocol deviation, progress reports, regulatory and administrative, any other business transacted.

24) Minutes of the meeting must be circulated among IEC members for concurrence. The same to be approved by the Chairman, IEC and tabled at the next IEC meeting for ratification.

25) Communication: All communications with/by stakeholders are encouraged to be in writing either by e-mail or hard copy. Oral communications should be limited to urgent matters and must be supplemented in writing later.

26) Stakeholders comprise IEC members, principal investigators, research team, base institution, sponsors, research participants/patients and regulatory & accreditation bodies. Member Secretary/IEC secretariat is responsible for prompt and proper
communication with each of them. This encompasses general circulars/letters on operational, regulatory and administrative matters; submission of reports/documents, etc.

4) **Responsible Person(s):** Chairman, Member Secretary and all members of IEC

5) **References:**

1. Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.
2. National Ethical Guidelines for Bio-medical and Health Research involving Human Participants
3. Good Clinical Practice Guidelines for Clinical Trials in India
4. ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose**: Process of record keeping and archival of the ethics committee documents.

2) **Scope**: Physical and electronic files of all documentation

3) **Procedure**:

   1) The ethics committee should prepare and maintain hard copies of its activities and documentation including the following for 5 years.

      a) Registration certificate/Re-registration of the ethics committee with Licensing Authority, policies and standard operating procedures should be documented and readily available in the ethics committee office for reference.

      b) Curriculum Vitae (CV) of all the members of the ethics committee, supporting documents, their affiliations, training completion certification should be documented and readily available with the ethics committee office.

      c) Details of the ethics committee secretariat staff.

      d) List of approved studies, minutes of the meeting, attendance of ethics committee members to the IEC meetings, action taken reports, ethics committee review and monitoring of study reports at site should be documented, duly signed and readily available at the ethics committee office.

      e) Copies of all research proposals reviewed and/or approved along with informed consent documents, progress reports submitted by the principal investigators, study team Curriculum Vitae’s, serious adverse event notifications received etc.

2) List of principal investigators at site with their curriculum vitae, medical registration certificates and GCP training completion certificates if any, should be readily available at the ethics committee office.

3) Copies of correspondences with ethics committee members, principal investigators, sponsors and other regulatory bodies should be filed as appropriate and should be available at the ethics committee office.
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4) Physical or electronic copies of all existing national and international regulations, guidelines on research ethics along with amendments should be readily available for reference.

5) Only persons who are authorized by the chairman and member secretary of the ethics committee will have access to the ethics committee documents/IT system/archived documents.

6) All the documents related to the ethics committee will be archived (Hard and Soft Copies) for a minimum period of 5 years in the institute, following the completion/termination of the study.

7) Documents will be dated, filed and archived (as appropriate) with proper label on top of file for easy identification of documents as per Cancer Institute (WIA) policy either at site or at third party location, as applicable.

8) All ethics committee documents are kept under lock and key at the ethics committee secretariat under the safe custody of member secretary. Only the member secretary and ethics committee secretariat will have access to these ethics committee official documents, for day to day function.

9) The ethics committee member secretary and secretariat will co-ordinate with regulatory authorities during the IEC inspection and audits, as appropriate.

10) Once the study is closed, the ethics committee will archive the documents as appropriate. The ethics committee will archive the documents for maximum period of five years from the date of site closure.

11) In case the study team requires access to these documents the principal investigator should write a letter to the Chairman/Member secretary, ethics committee with the purpose for which the access to the archived documents are required.

12) The policy of the IEC is strict access control of IEC documents to the member secretary and designated IEC secretariat.
13) Safety and security of IEC documents will be accorded utmost priority by restricting access to IEC secretariat by IEC secretariat staff only.

14) All electronic documents and soft copies will be available only in IEC Secretariat computers and will be password protected.

15) The IEC secretariat is given an exclusive official email id for its correspondences with access only to IEC secretariat staff.

16) Exchange of documents through email and their security and safety will be dealt with utmost care by strict access only by IEC secretariat staff.

4) **Responsible Person(s):** IEC

5) **References:**

   1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

   2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.

   3) Good Clinical Practice Guidelines for Clinical Trials in India

   4) ICH - E6 (R2): Good Clinical Practice (GCP).
1) **Purpose:** This SOP describes the process followed for preparation, approval, implementation and modification of IEC SOPs.

The IEC ensures that the processes followed are effective and efficient and in compliance to the provisions for clinical trials under Schedule Y of Drugs and Cosmetics Act 1940 & Rules 1945 as amended from time to time, National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants and Good Clinical Practice Guidelines for clinical Trials issued by ICMR and DGHRI, Govt. of India.

2) **Scope:** Applicable to standard operating procedures (SOPs) of IEC.

3) **Procedure:**

1) Member secretary, IEC will initiate action on need for development of required SOPs, modify the existing SOP’s subject to amendments to the current regulations, guidelines applicable to IEC. The process followed for creation and update of standard operating procedures is as follows.

A) **SOP Format**

   a) The header section of each page contains the ethics committee and cancer institute name, title of SOP, SOP Number, version date, effective date, prepared by, reviewed by and approval authority.
   b) The footer section of each page contains page number
   c) The font of SOP will be Times New Roman, 12 point.
   d) The text section is numbered using a standard format
   e) Each SOP may contain the following sections. Additional sections can be added as required

      1) Policy (as appropriate for SOP)
      2) Purpose: Defines the general area and how it is used.
      3) Scope: will describe specific tasks to be covered
      4) Procedures
      5) Responsible Person (as appropriate)
      6) References
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<td>SOP Title: Creation and Update of Standard Operating Procedures</td>
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<td>Member Secretary</td>
<td>Chairman</td>
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| Sign Date   | 12.12.2018 | Sign Date 12.12.2018 |

B) Revision, implementation and monitoring of SOP

a) Member secretary initiates action on SOP and place it in the agenda of the IEC meeting for discussion.

b) Member secretary will discuss with members of the ethics committee for the common agreement that the procedures and expectations are appropriate and achievable.

c) Refer appropriate regulations and guidelines and discuss with members, other experts to address opportunities, problems and concerns

d) Review for accuracy, completeness and appropriateness.

e) Have all the ethics committee members check the written procedures against actual practices before implementation. Chairman, ethics committee should approve all SOP’s and designate effective date

f) Train all the ethics committee members on new SOP and communicate on new SOP’s to the research personnel at Cancer Institute (WIA).

C) Monitor SOP’s regularly and make revisions appropriately

a) SOP’s should be reviewed annually or at appropriate time to ensure regulations and guidelines are up to date.

b) If determined that revisions are needed, follow the procedures described as above

c) Previous versions should be retained

d) Ensure that SOP’s are followed consistently over time

D) All the ethics committee members should undergo SOP Training within a specified period of time.
a) Training should be documented on training completion form

b) SOP should be accessible to the ethics committee members, research personnel at Cancer Institute (WIA) and sponsors.

4) **Responsible Person**: Member Secretary, IEC.

5) **References**:

1) Drugs and Cosmetics Act 1940 & Rules 1945, as amended from time to time.

2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants-2017

3) Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research