INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures
(Version 4)

Cancer Institute (WIA)
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INSTITUTIONAL ETHICS COMMITTEE (IEC)
CANCER INSTITUTE (W.I.A.)
EAST CANAL BANK ROAD, GANDHI NAGAR, ADYAR,
CHENNAI 600 020.

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.

INSTITUTIONAL ETHICS COMMITTEE (IEC) – CANCER INSTITUTE (W.I.A)
EAST CANAL BANK ROAD, GANDHI NAGAR, ADYAR
CHENNAI 600 020

STANDARD OPERATING PROCEDURE (SOP)
(CHAPTERS 1 TO 16)

Name	**: Dr. J. S. SATHYANARAYANA MURTHY**
Designation	: CHAIRMAN, IEC
Role performed	: APPROVAL OF SOP
Contact details	: No, 22/12, GST Road (Next to HARSHA Toyota Showroom) Guindy- Chennai 600 032 Mobile: 9841023438
Signature	
Date	: July 31st 2021

Name	**: Dr. R. SWAMINATHAN**
Designation	: MEMBER SECRETARY, IEC
Role performed	: REVIEW OF SOP
Contact details	: EPIDEMIOLOGY, BIOSTATISTICS AND CANCER REGISTRY CANCER INSTITUTE (W.I.A) Dr. S. KRISHNAMURTHI CAMPUS 38, SARDAR PATEL ROAD Chennai 600 036 Tel: 044-22209150 Ext 135 Fax: 044-22354508 Mobile: 9382197899
Signature	
Date	: July 27th 2021

Name	**: Mrs. VIDYA ANAND**
Designation	: ETHICS COMMITTEE COORDINATOR, IEC- SECRETARIAT
Role performed	: PREPARATION OF SOP
Contact details	: IEC- SECRETARIAT- CANCER INSTITUTE (W.I.A) 38, SARDAR PATEL ROAD, Chennai 600 036 Tel: 044-22209150 Ext 219 Fax: 044-22354508 Mobile: 9176950396
Signature	
Date	: 19th July 2021

INSTITUTIONAL ETHICS COMMITTEE (IEC)
CANCER INSTITUTE (W.I.A)
EAST CANAL BANK ROAD, GANDHI NAGAR,ADYAR
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Table of Contents

Ethics Committee and Ethical Principles

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Scope and Purpose

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) The Mission of Institutional Ethics Committee (IEC), Cancer Institute (WIA) 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.

3) **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.

4) 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 New Drugs and Clinical Trials Rules 2019 and with National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 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

Ethics Committee and Ethical Principles

The registration details of IEC are as follows:

Registration number: ECR/235/Inst/TN/2013
Re-registration number: ECR/235/Inst/TN/2013/RR-16
Re-registration number: ECR/235/Inst/TN/2013/RR-19

The IEC at the Cancer Institute (WIA) functions in accordance with New Drugs and Clinical Trials Rules 2019 and 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 now valid for 5 years. Re-registration of IEC should be done 3 months from the date of expiry. Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR)., has been granted (File No. - EC/NEW/INST/2020/856)
NABH Accredited IEC (File No. – EC-CT-2020-0141) Valid from 18th May 2020 till 17th May 2023.

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.

Ethics Committee and Ethical Principles

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 Executive Vice-Chairman 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.

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”.

Ethics Committee and Ethical Principles

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 vs benefits and 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.

Ethics Committee and Ethical Principles

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

Ethics Committee and Ethical Principles

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.

Ethics Committee and Ethical Principles

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.

Ethics Committee and Ethical Principles

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.

Ethics Committee and Ethical Principles

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

12. **References:**

1) The New Drugs and Clinical Trials Rules 2019
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.

Ethics Committee and Ethical Principles

Annexure - 1.1

Sr. No	Name of Member	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail I.D. and mailing address	Designation /Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1.	Dr. J. S. Sathyanarayana Murthy	MD (General Medicine) D.N.B (Cardiology); FACC, FRCP Specialty: Cardiology	Prof of Cardiology Sri Ramachandra University Porur	22/12, GST Road, Guindy, Chennai 600032 E mail: drjsnm@gmail.com Mobile: 9841023438	Chairman	Not affiliated to Cancer Institute(WIA)
2	Dr. R. Swaminathan	M.Sc., Ph.D.(Statistics), Ph.D. (Epidemiology)	Associate Director, Professor & Head, Dept. of Epidemiology, Bio-statistics & Cancer Registry. Cancer Institute (WIA) Chennai.	Cancer Institute (WIA), 38, Sardar Patel Road,Chennai 600 036. E mail: r.swaminathan@cancerinstitute.org Ph: 044-22209150 Extn: 135 Mob: 9382197899	Member Secretary	Affiliated to Cancer Institute(WIA)
3	Dr. Manoj Vasant Murhekar	MBBS; M.D (Preventive and Social Medicine)	Director- in-Charge, National Institute of Epidemiology, ICMR, Chennai Mob: 9444414663	National Institute of Epidemiology, ICMR, R-127, Tamil Nadu Housing Board, Ayapakkam, Chennai, 600077 E mail: mmurhekar@nieicmr.org.in mmurhekar@gmail.com	Clinician	Not Affiliated to Cancer Institute(WIA)

Ethics Committee and Ethical Principles

4	Dr. C. Suthakaran	MBBS, MD Speciality: Pharmacology	Professor Department of Pharmacology Savitha medical College & Hospital Thandalam Chennai 602105	Professor Department of Pharmacology Savitha medical College & Hospital Thandalam Chennai 602105 **Email:** drcsudha@gmail.com Mobile: 9884614153	Medical Scientist/ Pharmacologist	Not Affiliated to Cancer Institute (WIA)
5	Dr. S. Jagadesh Chandra Bose	MBBS;M.S (Gen. Sur); M.Ch (Sur. Onco) Specialty-Surgical Oncology	Professor & HOD Department of Surgical Oncology, Sri Ramachandra Medical College, Porur, Chennai	Professor & HOD Department of Surgical Oncology, Sri Ramachandra Medical College, Porur, Chennai Email: jeganbose@yahoo.com Mobile: 9381026868	Clinician	Not Affiliated to Cancer Institute(WIA)
6	Dr.S. Lakshminarasimhan	MD (Gen. Med)DM (Med. Onco)	Retd. Prof. & HOD, Medical Oncology, MMC, Institute of Obstetrics & Gynaecology, Chennai	Retd. Prof. & HOD, Medical Oncology, MMC, Institute of Obstetrics & Gynaecology, Chennai E Mail: drnarasimhan@rediffmail.com Mobile: 9841285090	Clinician	Not Affiliated to Cancer Institute(WIA)
7	Dr.Balasubramanian Ananthi	MD., DMRT Radiation Oncology	Associate Professor, Department of Radiation Oncology, Cancer Institute (W.I.A), Chennai	Department of Radiation Oncology, Cancer Institute (W.I.A) Email: ananthib@ymail.com Mobile: 9444886498	Clinician	Affiliated to Cancer Institute(WIA)
8	Dr. S. Padma	M.Sc. M.Phil. B.L. M.L. Ph.D.	Advocate High Court Chennai	F1, Thanikachalam Apts 63 Rakkiappa Street Mylapore Chennai 600 004 Email: padwin1@yahoo.co.in Mobile: 9444178456	Legal Expert	Not Affiliated to Cancer Institute(WIA)
9	Mrs. Sudha Ganapathy	M.A (Social Work) B.A	Retd, Prof & Head,	5D, Sunflower Ceebros Gardens, 38 Arcot Road,	Social Scientist	Not Affiliated to Cancer

Ethics Committee and Ethical Principles

		(Sociology)	Social Work Department, NIRT (formerly TRC), ICMR, Chennai	Virugambakkam Chennai 600 092 E mail: esgee70@gmail.com Mobile: 9884459194		Institute(WIA)
10	Mrs. Lata Ramakrishnan	M.A	Volunteer (non-staff), Cancer Institute (W.I.A) Chennai	4-A, 10 Downing 132, Greenways Road, R A puram Chennai 600 028 Email: lata.ramakrishnan@gmail.com Mobile:9962770880	Lay Person	Not Affiliated to Cancer Institute (WIA)

Procedure for constitution of IEC

1. **Purpose:** General procedure to constitute the ethics committee.

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

3. **Procedure:**

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

2. The ethics committee should be constituted in accordance with New Drugs and Clinical Trials Rules 2019 and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Good Clinical Practice Guidelines (GCP) for clinical trials in India.

3. The Executive Vice Chairman will ensure that the ethics committee is constituted in accordance with the New Drugs and Clinical Trials Rules 2019, National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants and Good Clinical Practice Guidelines for Clinical Trials in India.

4. The Executive Vice Chairman 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 Executive Vice Chairman 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. Members are appointed to the IEC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their

qualifications. (For eg. if the Chairperson is a Clinician, she or he can serve as both the Clinician and the Chairperson.)

9. 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, The New Drugs and Clinical Trials Rules 2019 and Good Clinical Practice Guidelines for Clinical Trials in India and other applicable national and international regulations and guidelines The appointment of an ethics committee member will be on voluntary service basis for a minimum period of 2 years. An Extension can be given for 2 more years depending on mutual consent.

10. Each member is required to sign confidentiality agreement and potential conflict of interest (COI) declaration form at the time of appointment regarding institutional ethics committee activities.

11. Members should be conversant with the provisions for clinical trials under The New Drugs and Clinical Trials Rules 2019, 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.

12. 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.

13. 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.

14. Executive Vice Chairman authorizes the independence of the ethics committee in its functioning and decision making.

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

16. At regular intervals the Executive Vice Chairman 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.

17. Any change in the composition of IEC will be intimated in writing to the Licensing Authority within 30 days

Criteria for selection of members of an IEC:

- Member should be selected based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IEC.
- Should be committed and understanding to the need of research and for imparting protection to participants in research.
- Willing to place his/ her full name, profession and affiliation to the IEC in the public domain

Condition of appointment:

- Each member of the IEC should provide a Signed CV, educational Certificates and their training certificates.
- Members are trained in Human research protection and/ or GCP at the time of induction into the IEC
- Read, Understand, accept and follow the COI policy of the IEC and declare it, if applicable, at the appropriate time.
- Sign a confidentiality and conflict of interest agreement/s

Issue date : 14.07.2021
Revision Date: 30.07.2024
Validity date: 3 years

18. Responsible Person(s): Executive Vice Chairman, Cancer Institute (WIA), IEC Members

19. References:

20. The New Drugs and Clinical Trials Rules 2019

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

22. Good Clinical Practice Guidelines for clinical trials in India.
17ICH - E6 (R2): Good Clinical Practice (GCP)

Procedure for appointing the members of the ethics committee

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 50% of the total members should be 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.

   5) **Terms of Reference:**

      The Executive Vice Chairman 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. Members will confirm their acceptance to the Executive Vice Chairman by providing all the required documentation for the membership of the ethics committee. The documents include signed CV, Educational certificates and their Training Certificates, sign a confidentiality and conflict of Interest agreements. The members will be apprised for their roles and responsibilities in the IEC through written communications from Executive Vice Chairman.

   6) Members should be committed and understanding to the need for research and for imparting protection to research participants in research.

   7) Members Should be willing to place her/his full name, profession and affiliation to the

Procedure for appointing the members of the ethics committee

IEC in the public domain

8) Members should be willing to volunteer the required time and effort for the IEC

9) Members should not have any known record of misconduct.

10. Members are required to provide a recent signed CV, educational certificates and their training certificates in human research protection and/or GCP at the time of induction.

11. The appointment of an ethics committee member will be on voluntary service basis for a minimum period of 2 years. An extension can be given for 2 more years depending on the mutual consent.

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

13. Members should be aware of relevant guidelines and regulations and be willing to undergo training or update their skills/knowledge during their tenure.

14. Members should be aware of their roles and responsibilities in ethics committee as per current regulations and national ethical guidelines. They will also be kept abreast of any changes in regulations, guidelines and IEC Standard Operating Procedures.

15. Each member is required to read, understand, accept and follow the Conflict of Interest (COI) policy of the IEC and require to sign confidentiality agreement and potential conflict of interest declaration form at the time of appointment regarding institutional ethics committee activities.

16. During the term, the Executive Vice Chairman 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 or if the member is a regular defaulter or in case of any misconduct.

17. Member will have the right to discontinue from membership of Institutional ethics committee. If any member wishes to withdraw from the IEC membership, he/she should inform the Chairman of the ethics committee one month in advance.

Procedure for appointing the members of the ethics committee

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

5) **References:**

1. The New Drugs and Clinical Trials Rules 2019
2. National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.
3. Good Clinical Practice Guidelines for Clinical Trials in India.

Training of New and Existing Members of the Ethics Committee

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:**

   1) Training Record: A record of training completed by the members of the IEC on provisions for The New Drugs and Clinical Trials Rules 2019, National Ethical Guidelines for Bio-Medical and Health Research involving Human Participants, Good Clinical Practice Guidelines for Clinical Trials in India.

   2) 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 The New Drugs and Clinical Trials Rules 2019, 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. members of the IEC should be conversant with provisions for clinical trials.

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 apprised of any amendments to the regulations and guidelines and IEC Standard Operating Procedures, as appropriate.

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

i) The New Drugs and Clinical Trials Rules 2019

ii) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

iii) Good Clinical Practice Guidelines for Clinical Trials in India

Training of New and Existing Members of the Ethics Committee

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 from time to time on The New Drugs and Clinical Trials Rules 2019, National Ethical Guidelines for Bio-Medical and Health Research Involving Human Participants, Good Clinical Practice guidelines for Clinical Trials in India and administration.

Training of New and Existing Members of the Ethics Committee

5) **Responsible Persons:** Executive Vice Chairman, Cancer Institute (WIA), Chairman and Member Secretary, IEC.

6) **References:**

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

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

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

4) The New Drugs and Clinical Trials Rules 2019.

Roles and Responsibilities of the Ethics Committee members

1) **Purpose:** To clarify on roles and responsibilities of the members of the Institutional ethics committee.

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

3) **Procedure**:

   1) All the IEC members should be trained to be knowledgeable about the current

      a) New Drugs and Clinical Trials Rules 2019

      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 with right to withdraw
      (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.

Roles and Responsibilities of the Ethics Committee members

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 in New Drugs and Clinical Trials Rules 2019

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

Roles and Responsibilities of the Ethics Committee members

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) Performance Evaluation of IEC: Performance Evaluation of ethics committee will be done by the Chairman. He/She will evaluate every member's performance and contribution based on attendance, inputs for review of protocols, SAEs reviewed, site monitoring visits etc.

15) The performance evaluation will be carried out during the last IEC meeting in a calendar year. The tool to be used for this is given in **Annexure 5.2.**

16) 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

17) 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.

18) 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.

19) Any important communication from the Licensing Authority to IEC on compliance issues/functions will be communicated to the Executive Vice Chairman, as appropriate

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

Roles and Responsibilities of the Ethics Committee members

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

5) **References:**

1) New Drugs and Clinical Trials Rules 2019
2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.
3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
4) ICH - E6 (R2): Good Clinical Practice (GCP).

Roles and Responsibilities of the Ethics Committee members

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

Roles and Responsibilities of the Ethics Committee members

review, for concurrence of IEC thereafter.

j) Obtaining prior scientific review, invite independent consultant, patient or community representative.

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

l) 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.

b) Essential Part of the Quorum.

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.

d) Essential part of the Quorum.

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

Roles and Responsibilities of the Ethics Committee members

international collaboration, compliance with regulations and guidelines.

b) Interpret and inform ethics committee members about new regulations and guidelines, if any.

c) Essential part of the Quorum.

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.

f) Essential part of the Quorum.

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 the Quorum.

Roles and Responsibilities of the Ethics Committee members

IEC Members Performance Appraisal / Contribution Form- CONFEDENTIAL Annexure 5.2

Assessors: Chairman and Member Secretary- IEC

Ethics Committee (EC) Member Assessment using a 5-point scale where 5 means excellent and 1 means very poor, is done following each question. Please put a ✓in appropriate box as assessment.

1. Attendance at the EC meetings was:

5= Excellent	4= Good	3= Fair	2= Poor	1= Very poor

2. Participation in discussion at the EC meetings was. .

5= Excellent	4= Good	3= Fair	2= Poor	1= Very poor

3. Willingness to participate in subcommittee for review of proposals and audit of trials.

5= Excellent	4= Good	3= Fair	2= Poor	1= Very poor

4. Involvement with the EC's tasks and functions was.

5= Excellent	4= Good	3= Fair	2= Poor	1= Very poor

5. I would rate His/hers overall performance on the EC as:

5= Excellent	4= Good	3= Fair	2= Poor	1= Very poor

He/ She can improve in the following areas:

Member Secretary Chairman

Procedure for Convening and Conducting the Ethics Committee Meeting

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) meeting that aids in IEC review of scientific aspects.

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

    3) The last date for submission of the study protocol documents to the ethics committee for review is at least three 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 the following circumstances, these studies may be taken up for direct IEC review.

        a) Retrospective studies of patients treated at the institute initiated by students/faculty of the institute.
        b) Surveys (online or otherwise) undertaken by faculty of the institute.
        c) Studies that involve sharing anonymised patient data collected retrospectively or prospectively for national or international collaborative studies or registries.
        d) All student thesis-these should be evaluated by the Institutional Thesis Review Committee before being submitted to the IEC.

Procedure for Convening and Conducting the Ethics Committee Meeting

e) Phd thesis – these will be evaluated by the respective research committee formed as per guidelines from the appropriate university.
f) Audit of treatment practices
g) Amendments of protocols already approved by IEC.

7) The member secretary/ethics committee secretariat forwards the soft copy of new study protocol documents/protocol amendments/others to all the IEC members 2 weeks 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 for ratification
iii a) Review of any approval by sub-committee for full committee ratification
iv. Review of action taken reports
v. Review of new submissions
vi. Review of re-submissions, if any
vii. Review of protocol amendments
viii. Review of notifications/others
ix. Review of regulatory and administrative Items
x. Additional agenda items, if any.
xi. 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.

Procedure for Convening and Conducting the Ethics Committee Meeting

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) Quorum required:

    a. A minimum of five members should be present.

    b. The quorum should include both medical, non medical or technical or/and non-technical members.

    c. Minimum one non-affiliated member should be part of the quorum.

    d. Preferably the lay person should be part of the quorum

    e. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

    f. No decision is valid without fulfilment of the quorum.

12. The quorum of the IEC during the meeting should be atleast 5 members with following representation.

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

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

14. 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.

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

16. If the quorum is not met on the day of the ethics committee meeting, the

Procedure for Convening and Conducting the Ethics Committee Meeting

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.

17. 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.

18. 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 in decision making.

19. Attendance at the ethics committee meeting is limited to the ethics committee members, secretariat staff and invited principal investigator/study representative/ study team.

20. 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.

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

22. Conduct of IEC Meeting may be face-to-face physical meeting or virtual in video mode or hybrid in nature, depending on the prevailing local circumstances. In Case of Special situation virtual or tele/web meetings should be initiated where face to face meetings can be avoided. Meeting could be digitally recorded (audio/video) or it has to be documented in the minutes, with permission of members and secretariat is responsible to note the attendance/ participation in the online meeting.

Procedure for Convening and Conducting the Ethics Committee Meeting

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

5) **References :**

1) New Drugs and Clinical Trials Rules 2019
2) National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants.
3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
4) ICH - E6 (R2): Good Clinical Practice (GCP).

Procedure for Submission of Research Proposals/others for Review

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, for 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 at least three weeks (21 days) in advance of the scheduled IEC meeting.

    4) Research proposals submitted within three weeks of the scheduled meeting will be reviewed in the subsequent ethics committee meeting.

    5) 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), NDCT Rules 2019.

    6) 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

Procedure for Submission of Research Proposals/others for Review

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

7. Plans for dissemination of the results of the study are welcome.

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

9. 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.

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

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

12. 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.

13. An acknowledgement will be issued by the IEC secretariat for all the notifications.

14. Protocol violation /deviation: Any protocol violation/ deviation should be reported to the IEC within two weeks from the time principal investigator becomes aware of the same

Procedure for Submission of Research Proposals/others for Review

15. All such reported protocol violation/deviation will be reviewed in the next scheduled IEC meeting for appropriate action.

16. The investigator report on protocol violation /deviation should describe root cause analysis, its adverse effect on safety, rights and wellbeing of research subject and on data collected for scientific validity with appropriate corrective and preventive action (CAPA) for review by IEC.

17. The IEC strongly recommends strict compliance to the approved study protocol to avoid protocol violation / deviation to protect research participant's rights, safety and wellbeing and scientific validity and study data integrity.

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.

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

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

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

5) The New Drugs and Clinical Trials Rules 2019

Procedure for Submission of Research Proposals/others for Review

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) Subject recruitment procedures: Equitable selection, 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.

Procedure for Submission of Research Proposals/others for Review

15) Investigators undertaking as per New Drugs and Clinical Trials Rules 2019 Table 4

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)

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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 scientific and 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 (Annexure 8.2). 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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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. Review check list given in Annexure 8.3.

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 /harms
   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) Subject recruitment arrangement to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.
   g) Management of research related injuries, adverse events etc.
   h) Compensation provisions
   i) Justification for placebo in control arm, if any.
   j) Availability of investigational products after the study, if applicable
   k) Patient information sheet and informed consent form in local languages
   l) Protection of privacy and confidentiality
   m) Involvement of the community, wherever necessary
   n) Plans for data analysis and reporting
   o) Compliance to all regulatory requirements and applicable guidelines
   p) Qualification, experience and Good Clinical practice (GCP) training completion of principal investigator and research team
   q) Resources, facilities and infrastructure at site for the proposed clinical trial/study
   r) Criteria for withdrawal of patients, suspending or terminating the study
   s) Procedure for change in principal investigator, research team, etc., if any.

8) Informed consent form should be verified whether it is in accordance with New Drugs and Clinical Trials Rules 2019 Table 3 for essential elements and format (Please see Annexure 8.1 of this SOP).

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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 (GCT)s/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 i.e The New Drugs and Clinical Trials Rules 2019.

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, as specified in the New Drugs and Clinical Trials Rules 2019 for conducting clinical trials (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.

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

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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, both soft and hard copies which are available in the secretariat as required. The same can also be accessed as below.
cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf

18) The evaluation of proposals or studies listed in SOP Chapter section

- Retrospective studies of patients treated at the institute initiated by students/faculty of the institute.
- Surveys (online or otherwise) undertaken by faculty of the institute.
- Studies that involve sharing anonymised patient data collected retrospectively or prospectively for national or international collaborative studies or registries.
- All student thesis-these should be evaluated by the Institutional Thesis Review Committee before being submitted to the IEC.
- Phd thesis – these will be evaluated by the respective research committee formed as per guidelines from the appropriate university.
- Audit of treatment practices
- Amendments of protocols already approved by IEC. , will be done by an IEC Sub Committee comprising Chairman, Member Secretary, one/two members outside the institute. Such proposals having free format comprising background, objectives, methods and references should be submitted to Institutional Ethics Committee Secretariat with a covering letter by PI signed by other Co- investigator and forwarded by HOD /Higher Authority. The proposals will be circulated among the Sub-committee members for review and approval. Such Transactions will be placed in the full committee for ratification.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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

5) **References:**

1) National Ethical Guidelines for Bio-medical and Health Research Involving Children issued by ICMR
2) National Guidelines for Stem Cell Research 2017.
3) National Health Policy 2017
4) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
5) ICH - E6 (R2): Good Clinical Practice (GCP).
6) Handbook for Applicants & Reviewers of Clinical Trials of New Drugs in India.
7) The New Drugs and Clinical Trials Rules 2019.

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8) **Checklist for Review of Informed Consent Documents** (As per The New Drugs and Clinical Trials Rules 2019)

Annexure 8.1

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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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. **Draft 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 :---------- Subject Name:----------
Date of birth /Age :----------
[Address of the subject ----------
Qualification----------
Occupation: Student / Self-employed/ Service / Housewife/ Others (Please tick as appropriate)
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. [ ]

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

(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 The New Drugs and Clinical Trials Rules 2019) Model has been given.

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) Lit 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.

1. 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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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) Over view 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 ethical 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,

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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, 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 handed 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.

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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

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 end points.

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 The New Drugs and Clinical Trials Rules 2019.

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.

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

Annexure 8.3

Review Checklist for EC Approval

Name of Study Protocol:

Name Principal Investigator:

Nature of Study: Clinical Trial/RCT/Clinical Research/ Basic Science /Field Study/ Student Thesis. (Please mark the relevant study)

---

1) Whether the study was approved by Scientific Advisory Committee (SAC) on scientific validity of the protocol?

   Date of Approval in SAC----------

2) Whether the study protocol poses any risk to the research participants? Yes / No

   If yes please specify:

3) Whether the selection of subjects meets fair and equitable selection criteria as per national ethical guidelines. Yes / No

4) Whether the patient information sheet provides all essential elements as per (The New Drugs and Clinical Trials Rules 2019) .for voluntary decision making of the patient? Specifically the following, (For Clinical trials)

Item	Yes / No/Not applicable	Remarks
Statement about research study		

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

risks and benefits of participation		
voluntary nature of study		
Privacy and Confidentiality		
alternative treatment option		
Travel reimbursement/ payment for participation if any		
Contact details of investigator and EC		
compensation in case of injury or death		
Subject rights and responsibilities		
Informed Consent in vernacular language		

5) Do you recommend any additional element/s in patient information sheet to protect the patients' rights, safety and wellbeing? Yes / No

   If yes please specify

6) Any conflict of interest?

Procedure for Reviewing the Research Proposals/others by the Ethics Committee Members

Investigator/ Institution: Yes /No Reviewer: Yes / No

7) Whether the clinical trial agreement (CTA) specifies the stakeholder's responsibilities, applicable regulations, ethical guidelines and insurance provisions for the compensation in case of injury or death related to the clinical trial? (review of all exclusions in the clinical trial insurance policy is mandatory) Yes / No

8) Whether this study requires regulatory clearance from the Drugs Controller General India?

Yes/ No

Signature of reviewer **Signature of Chairman/ Member Secretary**

Date: **Date :**

Procedure for Reviewing the Research Proposals involving Vulnerable Population

1) **Purpose:** Ethical review of the research proposals submitted by the **i**nvestigators 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.

Procedure for Reviewing the Research Proposals involving Vulnerable Population

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.

Procedure for Reviewing the Research Proposals involving Vulnerable Population

4)Responsible Person(s): Chairman, Member Secretary and all the members of the ethics committee

4) **References:**

1. National Ethical Guidelines for Bio-medical and Health Research involving Human Participants
2. National Ethical Guidelines for Bio-medical Research involving Children
3. Good Clinical Practice Guidelines for Clinical Trials in India
4. ICH - E6 (R2): Good Clinical Practice (GCP).
5. New Drugs and Clinical Trials Rules 2019

Procedure for Review of Serious Adverse Events (SAE)

1) **Purpose:** To review the Serious Adverse Events (SAE) of all clinical trials (Academic and Industry Sponsored)

2) **Scope:** Compliance to regulations, ethical guidelines
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 New Drugs and Clinical Trials Rules 2019

   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 New Drugs and Clinical Trials Rules 2019

   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 The New Drugs and Clinical Trials Rules 2019 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.

Procedure for Review of Serious Adverse Events (SAE)

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 (Cancer Institute WIA) as per New Drugs and Clinical Trials Rules 2019 Guidelines
   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 the investigational product;

   b) Violation of the approved study protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to the serious adverse event ;

   c) Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol.

   d) Not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo-controlled trial.

   e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.

Procedure for Review of Serious Adverse Events (SAE)

f) Adverse effect on a child in-utero because of the participation of the parent in the clinical trial.

g) Any clinical trial procedures involved in the study leading to serious adverse event

[Ref: The New Drugs and Clinical Trials Rules 2019]

13) (a) In any industry sponsored clinical trial, if any SAE-Injury or death occurs and to meet the reporting of the same within stipulated time to the Licensing Authority, the SAE report is forwarded to the subcommittee of following 4 persons for review under the expedited review category,

(i) Chairman
(ii) Member Secretary
(iii) Basic Medical Scientist
(iv) Clinician

(b) After thorough review by subcommittee, the decision on causality and associated compensation, if any, are minuted and report submitted to the licensing authority within prescribed timelines i.e. within 30 days (Ref: The New Drugs and Clinical Trials Rules 2019)

(c) The minutes of the findings of the subcommittee are then circulated among other ethics committee members for information and discussed in the forthcoming ethics committee meeting for approval.

(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 in academic clinical trials, they will be reviewed in the forthcoming IEC meeting for decision on compensation and necessary action.

15) The IEC will refer The New Drugs and Clinical Trials Rules 2019 for current guidance on formulae for compensation for the SAE of Injury and Death in clinical trials.

Procedure for Review of Serious Adverse Events (SAE)

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

17) All ethical review points will be documented in minutes of the meeting of IEC.

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

5) **References:**

1) National Ethical Guidelines for Bio-medical Research involving Children
2) Guidance Document on SAE from CDSCO.
3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
4) ICH - E6 (R2): Good Clinical Practice (GCP).
5) The New Drugs and Clinical Trials Rules 2019.

Procedure for Conflict of Interest Disclosure

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 New Drugs and Clinical Trials Rules 2019 for registration of the ethics committee, point number (10) 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 New Drugs and Clinical Trials Rules 2019, 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.

Procedure for Conflict of Interest Disclosure

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) New Drugs and Clinical Trials Rules 2019

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).

Procedure for Conflict of Interest Disclosure

Template

To,

The Chairman,

Institutional Ethics Committee,

Cancer Institute (W.I.A)

Adyar, Chennai 600 020

Conflict of Interest declaration form

As a member Institutional Ethics committee, Cancer Institute (WIA), I am aware of the policy of the ethics committee regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the Institutional Ethics Committee.

I declare conflict of interest in relation to the proposal entitled ----------

---

Submitted for review to the ethics committee. The reason for conflict of interest is ----------

I will refrain from the review process and/or discussion at the ethics committee meeting/and also will not take part in ongoing and periodic review and monitoring of this study.

Signature of the Member with date

Procedure for Expedited Review

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 study 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 research 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 four members. Chairman, member secretary and two members as designated by the chairman/member secretary will normally be the sub-committee. This is applicable for retrospective studies also. All the three members should be present for the meeting (face-to-face or tele/video conference) and should declare no conflict of interest. Chairman/Member Secretary may choose to circulate the proposals classified under expedited review to full committee, as deemed fit.

   4) The sub-committee should review all the documents as per governing regulations under expedited review. In addition, the PI must clearly state the reason (s) seeking for 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.

Procedure for Expedited Review

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) New Drugs and Clinical Trials Rules 2019
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).

Procedure for Expedited Review

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 left-over 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

g. 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.

CANCER INSTITUTE (W.I.A) Institutional Ethics Committee				
Version No: 04	Issue Date 14.07.2021	Effective Date 31.07.2021	Mandatory Review 30.07.2024	SOP Number: CI/IEC/SOP/13

REVIEW FOR STUDIES DURING EMERGENCY SITUATIONS/DISASTERS/EPIDEMICS

1) **Purpose: Review for studies during Emergency Situations**

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

3) **Procedure:**

1. Expedited Review

1.1. In view of the potential need for ethical review of certain studies in emergency situations/disasters/epidemics at Cancer Institute (WIA), the Institutional Ethics Committee of Cancer Institute (WIA) is empowered to undertake an Expedited review of such studies as per Section 12 of SOP of the IEC (Expedited Review Category clause of the Standard Operating Procedures)

1.2. The proposals which needs ethical clearance should be submitted to IEC for expedited review along with a clearance from the Institute/ HOD

1.3. The IEC Covering letter and the protocol of the study should clearly specify the means and methods adopted for protecting both researchers and participants from risk of infection and/or stigma/loss of privacy/loss of confidentiality.

2. Conflict of Interest:

The researchers/ Ethics Committee members should declare the Conflict of Interest before the commencement of the virtual/ Physical meeting.

3. Content Requirements for Submission:

3.1 Covering letter with a request explaining why Expedited review is needed

3.2 Checklist which indicates the list of attachments

3.3 Full proposal (this can also be an abbreviated version which specifies objectives, methodologies proposed, their justification and the means used to protect participants and researchers)

3.4 Informed consent forms (in English and languages which are applicable – the translations for multi-site studies can be subsequently submitted) In case there are several data collection methods used, informed consent forms must match each of the data collection methods being used. In case the same ICF is used across multiple data collection methods, the ICF and covering letter should indicate the same.

REVIEW FOR STUDIES DURING EMERGENCY SITUATIONS/DISASTERS/EPIDEMICS

3.5 Permissions, wherever applicable, Insurance certifications, wherever necessary Memorandum of Understanding (MOU) wherever necessary
3.6 Materials Transfer Agreement (MTP) or Terms of Reference being offered for transfer of biological materials wherever necessary with the institution undertaking the testing.
3.7 An appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance (addressing issues of confidentiality, sharing of data, joint publications, etc)
3.8 Updated CVs of all researchers.

4. Method of submission of proposals to IEC for review

4.1 A soft copy of the documents in a pdf format can be sent to the IEC Secretariat email id: iec@cancerinstitutewia.org.
4.2. The covering email to the IEC Member Secretary should also mention the following:
1. Title of the study
2. Objectives
3. Name of the PI with Designation along with detailed CV
4. Name of the Co- PI's with Designation
5. Duration of the study

5. Ethics Review:

5.1 Researchers can submit the research proposals electronically and those research proposals and relevant documents will be screened by the secretariat for completeness and in discussion with member secretary can be categorized as exempt/ expedited review/ full committee review depending on the urgency and need.

5.2 Virtual or Tele / Video meetings should be attempted in case the face- to face meetings may not be possible due to public health restrictions like (Lock downs, assembly of persons etc). Quorum for decision-making should have a minimum of five members, including both medical/non-medical and technical/non-technical members with one non-affiliated member. The Chairman opens the meeting, determine the quorum, COI declaration and summaries the agenda to the other members.

REVIEW FOR STUDIES DURING EMERGENCY SITUATIONS/DISASTERS/EPIDEMICS

5.3 During the review process, the Ethics Committees should consider the following:

A. If written consent is not possible (e.g., physical isolation/severe COVID-19 patients), consent could be given orally/ use electronic methods to document and record.

B. Due to inability of the participant to attend the site (for e.g., social distancing), the contact/communication can be made via phone, to enquire and identify adverse events, serious adverse events and ensure medical care and oversight with documentation.

C. In an ongoing study, if the designated principal investigator (PI) is indisposed for a period, she/he may need delegate parts of her/his duties temporarily to others/ co-investigator and the same should be documented and reported to EC at the earliest.

5.4. EC members present during the virtual meeting should decide through consensus or cast online vote expressing their decision. Any disagreement to be recorded with reasons. Meeting could be digitally recorded (audio/video) with permission of members and secretariat is responsible to note the attendance/ participation in the online meeting.

6. Process to be followed for such submissions

6.1. All such submissions shall be treated in keeping with the existing processes for expedited review with a changed time frame of about 72 hours.

6.2. The IEC Member Secretariat staff can communicate with the Chairperson and Member Secretary with regard to potential reviewers for such studies and keep an available list of potential reviewers.

6.3. On receipt of proposals by the Member Secretary, they should be forwarded to the designated reviewers.

7. Tentative turnover time

7.1. The IEC should try to complete the review in 72 hours.

7.2. This time frame is tentative and will also depend on the complexity of the study.

8. Approval process

8.1. Approval shall be granted by the Member Secretary if all comments in the feedback are reasonably addressed or plausible explanations are provided for the inability to address them.

8.2. This approval can be electronically transmitted if they cannot be collected in person.

8.3. All such approvals and the revisions required thereof requires to be ratified in the subsequent full committee meeting of the IEC

REVIEW FOR STUDIES DURING EMERGENCY SITUATIONS/DISASTERS/EPIDEMICS

9. Record keeping

9.1. All documentation from the submission to the final approval shall be preserved electronically.

9.2. One copy of the final approved proposal and all the other accompanying submissions should be maintained in the paper form.

9.3. Communications such as minutes, approval from Chairman, shall be printed and treated as minutes of the meeting.

One set in printed form should be preserved as minutes of the process.

9.4. All other existing regulations regarding record keeping will continue to apply.

10. Compensation for research-related harm:

10.1 Research participants who suffer direct physical, psychological, social, legal or economic harm as a result of participating in the research are entitled to free health care and referrals as needed. However, for research related Serious Adverse Events (SAE), appropriate financial compensation and insurance coverage be provided as per norms.

10.2 Sponsor to include insurance coverage/other provision within budget. In investigator initiated research, investigator/institution must provide through insurance, grants

10.3 SAEs should be reported to EC (including on non-working days) within 24 hours and a report on SAE relatedness (causality assessment) within 14 days for EC review regarding quantum and type of assistance.

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

2) **References :**

1) National Guidelines for Ethics Committees Reviewing Biomedical & Health Research- During COVID-19 Pandemic- April 2020
2) New Drugs and Clinical Trials Rules 2019
3) Good Clinical Practice (GCP) Guidelines for Clinical Trials in India.
4) ICH - E6 (R2): Good Clinical Practice (GCP).
5) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. New Delhi: Indian Council of Medical Research; 2017. Available from: (http://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf). (Last accessed on 28th April 2020)

Procedure for Decision Making on Research Proposals/others

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 New Drugs and Clinical Trials Rules 2019) is complete at least five members with the following representations.

Procedure for Decision Making on Research Proposals/others

(i) Basic medical scientist
(ii) Clinician
(iii) Legal expert
(iv) Social scientist
(v) Lay person

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 within 7 working days 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.

Procedure for Decision Making on Research Proposals/others

15) Approvals generally should be within 7 working days from the date of IEC meeting this applies to protocol amendments with specific mention of modified 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 New Drugs and Clinical Trials Rules 2019 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, equitable selection of subjects and standards.

Procedure for Decision Making on Research Proposals/others

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 two members along with the Secretariat staff 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.

Procedure for Decision Making on Research Proposals/others

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.

27) Research participant grievance and redressal process: The Institutional Ethics Committee (IEC) Secretariat is the point of contact for addressing all complaints.

28) The IEC Secretariat contact details are displayed in patient charter in prominent research areas (clinical trial ward, consenting areas etc.) of the Cancer Institute (WIA) for complaints and redressal.

29) Current, past and potential research participants or their representatives can meet the member secretary in person for any research related clarification, issues and complaints. The research participant must support his complaint or concern in writing.

30) The IEC secretariat will attend to the participant and collect the complaint and forward the complaint to the member secretary for necessary action.

31) Member secretary will address the research participant complaint or concern as appropriate, to protect the rights, safety and wellbeing of research participant.

32) The member secretary will consult chairperson if required for constituting a subcommittee of three members to attend to the complaint and take appropriate action.

Procedure for Decision Making on Research Proposals/others

33) All decisions /actions taken will be tabled in IEC meetings for information.

34) A report on the same is forwarded to the Head of the institute for information and record.

35) All complaints about IEC functioning should be addressed in writing to the Executive Vice Chairman, Cancer Institute (WIA), Chennai for redressal.

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

5) **References :**

1. National Ethical Guidelines for Bio-medical and Health Research involving Human Participants
2. Good Clinical Practice Guidelines for Clinical Trials in India
3. ICH - E6 (R2): Good Clinical Practice (GCP).
4. The New Drugs and Clinical Trials Rules 2019

Procedure for Record Keeping and Archival of Ethics Committee Documents

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

Procedure for Record Keeping and Archival of Ethics Committee Documents

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) The items under **archival and retrieval record** should have minimum, the following:

A. Serial number

B. Name of the protocol

C. Name of the principal Investigator

D. Name of the sponsor/ CRO

E. Date of site closure

Procedure for Record Keeping and Archival of Ethics Committee Documents

F. Date IEC archival of study documents

G. Period of archival from effective date

H. Location of archival

I. Authorized person to contact for retrieval of record.

12) IEC Secretariat should maintain record of pest control certification of archival area, maintain fire extinguishers for preventive measures and fire safety certificates for audit purpose.

13) The access to the archived documents will be recorded in the same record with details on date of access, purpose and appropriate signatures for compliance and audit purpose.

14) 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.

15) The policy of the IEC is strict access control of IEC documents to the member secretary and designated IEC secretariat.

16) Safety and security of IEC documents will be accorded utmost priority by restricting access to IEC secretariat by IEC secretariat staff only.

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

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

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

Procedure for Record Keeping and Archival of Ethics Committee Documents

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

5) **References :**

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

2) Good Clinical Practice Guidelines for Clinical Trials in India

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

4) The New Drugs and Clinical Trials Rules 2019

Creation and update of Standard Operating Procedures

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 New Drugs and Clinical Trials Rules 2019 National Ethical Guidelines for Bio-medical and Health Research Involving Human Participants and Good Clinical Practice Guidelines for clinical Trials issued by ICMR 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.
         b) The footer section of each page contains page number
         c) The font of SOP will be Calibri, 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

Creation and update of Standard Operating Procedures

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.

Creation and update of Standard Operating Procedures

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

5) **References:**

1) New Drugs and Clinical Trials Rules 2019.

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

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