Standard Operating Procedures

of

ICMR-NIRRCH Ethics Committee for Human Studies

SOP- Version 7,
8th November 2024

ICMR | NIRRCH
INDIAN COUNCIL OF MEDICAL RESEARCH | NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH

National Institute For Research In Reproductive and Child Health

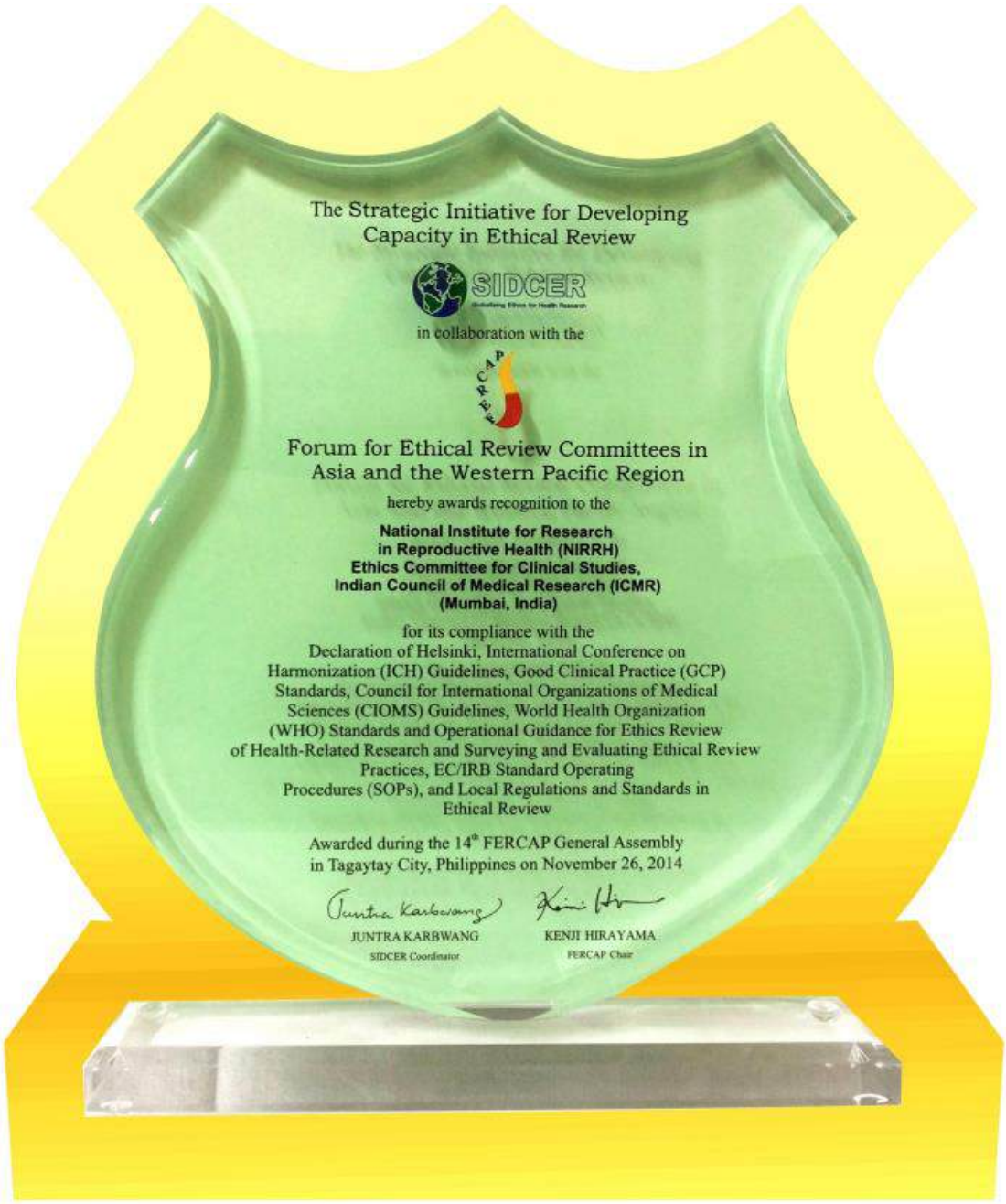
Accreditation and Registrations

The ICMR-NIRRCH Ethics Committee for Human Studies has been recognized by

- **Strategic Initiative for Developing Capacity in Ethical Review - Forum for Ethical Review Committees in Asia and the Western Pacific Region (SIDCER – FERCAP) in 2014 and re-recognized in 2017 and 2021.**

The following national and international agencies recognize the ICMR-NIRRCH ethics committee for Human Studies

- **Central Drugs Standard Control Organization (CDSCO)**
- **Department of Health Research (DHR)**
- **Office for Human Research Protections (OHRP)**


The Strategic Initiative for Developing Capacity in Ethical Review
SIDCER
in collaboration with the
FERCAP
Forum for Ethical Review Committees in Asia and the Western Pacific Region
hereby awards recognition to the
National Institute for Research in Reproductive Health (NIRRH) Ethics Committee for Clinical Studies, Indian Council of Medical Research (ICMR) (Mumbai, India)
for its compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review
Awarded during the 14th FERCAP General Assembly in Tagaytay City, Philippines on November 26, 2014
JUNTRA KARBWANG
SIDCER Coordinator
KENJI HIRAYAMA
FERCAP Chair

The Strategic Initiative for Developing Capacity in Ethical Review

SIDCER
Globalizing Ethics for Health Research

in collaboration with the

FERCAP

Forum for Ethical Review Committees in Asia and the Western Pacific Region

hereby renews recognition of the

National Institute for Research in Reproductive Health (NIRRH) Ethics Committee for Clinical Studies, Indian Council of Medical Research (ICMR) (Mumbai, India)

for its compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review

Awarded during the 17th FERCAP General Assembly in New Delhi, India on November 22, 2017

JUNTRA KARBWANG
SIDCER Coordinator

KENJI HIRAYAMA
FERCAP Chair

The Strategic Initiative for Developing Capacity in Ethical Review

SIDCER
Globalizing Ethics for Health Research

in collaboration with the

FERCAP

Forum for Ethical Review Committees in Asia and the Western Pacific Region

hereby renews recognition of the

National Institute for Research in Reproductive & Child Health (ICMR-NIRRCH) Ethics Committee for Human Studies (Mumbai, India)

for its compliance with the Declaration of Helsinki, International Council for Harmonisation (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review

Awarded during the 21st FERCAP General Assembly in Yogyakarta, Indonesia (via Zoom) on December 11, 2021

JUNTRA KARBWANG
SIDCER Coordinator

KENJI HIRAYAMA
FERCAP Chair

Background

ICMR-NIRRCH Ethics Committee for Human Studies is an independent body constituted of non-affiliated Chairperson along with varied affiliated as well as non-affiliated members from medical, non-medical, scientific, non-scientific, legal & social-science backgrounds whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in the research/ trial, by reviewing, approving and providing a continuing review of the research protocols and amendments. It ensures the effective implementation of National & International Ethical guidelines for researchers engaged in Clinical, Biomedical, Operational & Implementation Research that involves Human Study participants.

The Ethics Committee for Clinical Studies involving Human Participants was established in the Institute for Research in Reproduction (formerly known as IRR) in October 1994. In February 2022 the NIRRH Ethics Committee for Clinical Studies was renamed as ICMR-NIRRCH Ethics Committee for Human Studies.

The first version of the IEC's standard operating procedures (SOP) was prepared in 2014. It helped standardize procedures and lay a sound foundation for the day-to-day practices of our institute's conduct of ethical research. The SOP is revised periodically to ensure compliance with the evolving guidelines.

The review process ensures that the documents are submitted to the IEC secretariat at least 3 to 4 weeks before IEC meeting. IEC Secretariat checks for the completeness of the project proposal concerning the information, methodology, informed consent documents, and signatures of the Principal and Co-Investigator/ Collaborators along with the necessary scientific review/ approval. The member secretary then assigns the project to appropriate reviewers (Expertise as per the subject of the Research Project) & the documents are mailed to the reviewers at least 10 days before the meeting date.

The following criteria are considered while reviewing the study protocol:

- Minimize risks to participants
- Participants are selected equitably
- Risks must be reasonable concerning anticipated benefits Informed consent is adequate, easy to understand, and properly documented
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate;
- Appropriate safeguards are included to protect vulnerable participants.
- Informed consent is appropriate, easy to understand, and properly documented
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
- Ensure that the research project does not induce the participants to be lured into the research/ clinical trials and that the researcher has a recruitment policy to ensure an unbiased selection of an adequate number of suitable participants according to the protocol

Prof. Shubhada Chiplunkar
Former Director ACTREC-TMC

Preface

With immense pleasure, I write the preface for the revised edition (Version 7.0) of the SOPs (Standard Operating Procedures) for IEC. The ICMR-NIRRCH Ethics Committee for Human Studies serves a great purpose in effectively implementing Ethical guidelines for researchers engaged in Clinical, Biomedical, Operational, and Implementation Research involving Human Study participants.

.Dr. Ragini Kulkarni, former Member Secretary, and Dr. Usha Saraiya, former Chairperson of IEC, NIRRH, Mumbai, spearheaded the creation of the First Edition of SOPs in 2014. Subsequently, Dr. Beena Joshi, former Member Secretary, and Dr. Padmavathy Menon, former Chairperson, led the development of the updated edition.

This comprehensive document covers the entire mandatory requirement as per the regulatory guidelines. Faculty and researchers at the institute found it beneficial to submit it to the IEC for approval. The Director of ICMR-NIRRCH, Mumbai, also appreciated the effort, noting that it was well-received by the researchers and scientists of NIRRCH over time.

The need to update the SOPs arose due to evolving global requirements and new guidelines led by the ICMR Bioethics division. A core team consisting of a Member Secretary and two Ethics Members with thorough knowledge of ethics was formed to draft the revised SOPs.

In-depth deliberation and inputs from the SOP team members have led to a revision of SOPs. The draft SOPs were circulated to members of the IEC for their input. On record, I would like to sincerely thank the core group members for drafting revised SOPs, members of IEC, and distinguished researchers & scientists of ICMR-NIRRCH for their valuable inputs. Director, ICMR-NIRRCH, Dr. Geetanjali Sachdeva also gave useful inputs for which she deserves appreciation. Special thanks to Dr. Vikrant Bhor, Member Secretary, IEC, Dr. Bhakti Pathak, Jt. Member Secretary Dr. Suchitra Surve, Ex.Jt. Member Secretary, IEC, and Dr. Beena Joshi, Ex-Member Secretary, IEC for revision of SOPs.

The document is now ready for release. The updated SOPs are user-friendly and will help researchers and scientists at ICMR-NIRRCH submit their proposals to the IEC for approval.

Dated: 8.11.2024
Place: Mumbai

(Dr. Shubhada Chiplunkar)
Chairperson, IEC, ICMR-NIRRCH, Mumbai

Acknowledgment

The NIRRCH Ethics Committee for Human Studies involving human participants was established in 1994. To date, six ethics committees have been functional following national and international guidelines for research involving human participants. At the outset, we express gratitude and acknowledge the contributions of all our previous Ethics committee members for the smooth functioning of our IEC.

The first version of the SOP was constituted in 2014 which helped us standardize procedures and lay a sound foundation for the ethics practices in research at our Institute. We gratefully acknowledge the contributions of the SOP team for revising the SOPs.

We extend our heartfelt thanks to Dr. Ragini Kulkarni and Dr. Beena Joshi, former IEC member secretaries for their significant contributions, time, and effort in formulating and revising the SOPs.

The administrative support extended by Mrs. Zakia Ansari, Ex-Secretariat staff Mrs. Vaishali Bhogate, and Mr. Sasikumar is duly recognized.

We especially thank the IEC Chairperson, Dr. Shubhada Chiplunkar, and Ex-Chairperson, Dr. Padmavathy Menon for their guidance and valuable input. We are grateful to the Director, ICMR-NIRRCH, Dr. Geetanjali Sachdeva, for her continued guidance and support.

The revised SOPs have some major modifications, especially in the project submission forms, guidelines, and timelines for submitting and reporting to the IEC, references to websites for new guidelines on various aspects of ethics in research, and a new chapter on on-site monitoring and post-monitoring activities.

We hope that these revised SOPs for the functioning of the IEC will be useful in upholding the procedures for conducting ethical practices in research at the Institute.

Dr. Vikrant Bhor
Member Secretary
IEC, ICMR-NIRRCH, Mumbai

Dr. Bhakti Pathak
Joint Member Secretary
IEC, ICMR-NIRRCH, Mumbai

Contents

LIST OF ABBREVIATIONS

Acronym	Full Title/Description
AAHRPP	Association for the Accreditation of Institutional Research Protection Programs
ADR	Adverse Drug Reaction
AE	Adverse Event
BARC	Bhabha Atomic Research Centre
BE	Bio-equivalence
BIS	Bureau of Indian Standards
CDC	Center for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CoI	Conflict of Interest
CONSORT	Consolidated standards of reporting trials

CRF	**Case Record Form**
CRO	**Contract Research Organization**
CTA	**Clinical Trial Agreement**
CTRI	**Clinical Trial Registry of India**
DAE	**Department of Atomic Energy**
DBT	**Department of Biotechnology**
DCGI	**Drug Controller General of India**
DCR	**Drugs and Cosmetic Rules, 1945**
DGFT	**Directorate General of Foreign Trade**
FDA	**Food and Drug Administration**
FDC	**Fixed-Dose Combination**
FERCAP	**Forum for Ethical Review Committees in Asia and the Western Pacific Region**
GCP	**Good Clinical Practice**
GEAC	**Genetic Engineering Approval Committee**

GLP	**Good Laboratory Practices**
GMP	**Good Manufacturing Practices**
HIPAA	**Health Insurance Portability and Accountability Act**
HMSC	**Health Ministry Screening Committee**
IAEA	**International Atomic Energy Agency**
IB	**Investigator's Brochure**
IBSC	**Institutional Bio Safety Committee**
IEC	**Institutional Ethics Committee**
ICF	**Informed Consent Form**
ICH	**International Committee on Harmonization**
ICMR	**Indian Council of Medical Research**
IC-SCR	**Institutional Committee for Stem Cell Research**
IDE	**Investigational Device Exemption**
IMDRA	**Indian Medical Devices Regulatory Authority**

IND	**Investigational New Drug**
IRB	**Institutional Review Board**
ISI	**Indian Standards Institute**
MoU	**Memorandum of Understanding**
MTA	**Material Transfer Agreement**
NAC-SCRT	**National Apex Committee for Stem Cell Research and Therapy**
NDA	**New Drug Application**
NIH	**National Institutes of Health**
NOC	**No-objection Certificate**
OHRP	**Office for Institutional Research Protections**
PI	**Principal Investigator**
PIS	**Participant Information Sheet**
RCGM	**Review Com-mittee on Genetic Manipulation**
RCT	**Randomized Controlled Trial**

SAE	**Serious Adverse Event**
SOPs	**Standard Operating Procedures**
SRC	**Scientific Review Committee**
WHO	**World Health Organization**
WMA	**World Medical Assembly**

BIBLIOGRAPHY

1. **International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.**
2. **World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.**
3. **WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000)**
4. **Ethical Guidelines for Biomedical Research on Human Participants, ICMR, 2006**
5. **WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011**
6. **Declaration of Helsinki 2013**
7. **Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial, CDSCO, MOHFW, 9th Jan 2014**
8. **ICH GCP E6(R2) Good Clinical Practice: Consolidated Guidance, 2016**
9. **Council for International Organizations of Medical Sciences 2016**
10. **Guidance for managing Ethical Issues in Infectious Disease outbreaks (WHO-2016).**
11. **National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR, 2017.**
12. **National Ethical Guidelines for Biomedical Research Involving Children, ICMR 2017**
13. **ICMR Stem cell 2017**
14. **ICMR common forms for ethical review, 2018.**
15. **US revised Common Rules 2019**
16. **New Drugs Clinical Trial Rules 2019**
17. **SIDCER FERCAP meeting minutes template, 2020**
18. **SIDCER FERCAP Agenda template, 2020**
19. **SIDCER FERCAP Assessment form template, 2021**
20. **Guidelines for usage of leftover De-identified/ Anonymous Samples for Commercial purposes,2023**
21. **Guidance on Ethical requirements for Laboratory validation testing, 2024**

22. **Ethical requirements for systematic review and meta-analysis proposals,2024 (An addendum to ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017)**
23. **Ethical Considerations for submission of Research Data to the ICMR Data center, May 2024**
24. **Dissolving the National Apex Committee for Stem Cell Research and Therapy issued by the Department of Health Research, March 2024**

GLOSSARY

Active Study File	**Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study**
Administrative Documents	**Documents include official minutes of IEC meetings and the Standard Operating Procedures, both historical files and Master Files**
Agenda	**A list of things to be done; a program of business at a meeting**
Amendment protocol	**A package of the amended parts and related documents of Package, the protocol, previously approved by the IEC. During the study, the Principal Investigator may decide to make changes in the protocol.**
Approved Protocols	**Protocols that have been *approved without stipulations* or *approved with recommendations* by the IEC may proceed. Protocols that have been *approved with stipulations* by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within *one* month for re-review.**
Audit	**A systematic and independent examination of research trial approval activities and documents to determine whether their view and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements**
Clinical trial office	**An institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached**
Conference	**A meeting of individuals or representatives of various organizations to discuss and/or act on topics of common interest.**
Confidentiality	**Prevention of disclosure, to other than authorized individuals, of IEC/IRB's information and documents**

Confidentiality Agreement (Secrecy or Nondisclosure agreements)	**An agreement designed to protect, information, data and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. The recipient must include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.**
Conflict of Interest	**A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.** **Conflict of interest is present and interferes with the ability to make an objective evaluation when ethics committee members** **Have their research projects under review by the Ethics Committee, when they are an investigator, co-investigator, or when they are in a supervisory or mentoring relationship with a Principal Investigator.** **Members whose spouse/relative is a Principal Investigator or co-investigator, for any project under review are also considered to have a conflict of interest.** **Members may also have conflict of interest situations when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, or organization that may be the sponsor of the research project, or that may be substantially affected by the research.** **To maintain the independence and integrity of research ethics review, members must identify, eliminate, minimize or otherwise manage real, potential or perceived conflicts of interest.** **If a member has a personal or financial conflict of interest the members must disclose the nature of the conflict and absent themselves from any discussion or decision regarding that research project. If a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee can ensure that an alternate member is in attendance to maintain quorum. There are three key elements in this definition: financial interest; official duties; professional and personal interest.**

Conflict of interest occurs when	1. **An individual's private interest differs from his or her professional obligations to the institute.** 2. **Professional actions or decisions occur that an independent observer might reasonably question.** 3. **A conflict depends upon the situation and not on the character or actions of the individual.** 4. **Potential conflicts of interest must be disclosed and managed as per policy.**
CRF	**Case Record Form or Case Report Form is a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial participant.**
Deviation / Non - compliance / Violation	**The IEC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, national and international guidelines or regulations, and/or fail to respond to the IEC request for information/action.**
Document	**Documents mean the following:** **- Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews)** **- IEC documents (SOPs, meeting minutes, advice and decisions)** **- Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.**
Expedited approval	**An IEC approval granted only by the Chairman & assigned EC members of the IEC (not the full Board) for minor changes to new/ current IEC approved research activities and for research which involves not more than minimal risk.**
ICD	**Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate**

IEC	**Institutional Ethics Committee is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety, and well-being of human participants involved in a trial and to provide public assurance of that protection.**
IEC members	**Individuals serving as regular and alternate members of the institute's Ethical Committee. These committees are constituted in accordance with the EC membership requirements outlined in ICH GCP.**
IEC representatives	**Many IECs rarely find time to perform monitoring visits themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IEC**
Inactive Study Files	**Approved and supporting documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to participants, scientific evaluations) that correspond to each study approved by the NIRRCH Ethics Committee for Human Studies for which a final report has been reviewed and accepted.**
IND	**Investigational New Drug is a drug that has never been seen in the market because it is under investigation for its efficacy and safety and has not yet been approved for marketing by the local authorities. The drug is therefore approved for use only at certain study sites**
Independent Consultant	**An expert who provides advice, comments and suggestions after reviewing study protocols without any affiliation to the institutes or investigators proposing the research.**
Inspection	**The act by some regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities**

Legally Authorized Representative (LAR)	**A LAR is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure as per research protocol.**
Majority vote	**A Consensus procedure is carried out if one-half plus one member of the required quorum votes in its favor.**
Master file	**A file for storage of the originally signed and dated documents**
Master SOP files	**An official collection of the institute's standard operating procedures (SOP) accessible to all staff, IEC members, auditors and government inspectors as a paper copy with an official stamp on first and last page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered official.**
Meeting	**Deliberations between at least three (3) persons where such deliberations determine or result in the joint conduct or disposition of business.**
Minutes	**An official record of the business discussed and transacted at a meeting, conference, etc.**
Monitoring visit	**An action is that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting research, taking care of participants, recording data, and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visits will be arranged in advance with the principal investigators.**
Non-members of the IEC	**Any relevant person/persons who presently is/are not a member/members of the IEC such as authorities, monitors, auditors, participants, etc.**
Project Review Form	**An official record that documents the review process for Revised & Amendment Protocols as well as Continuing Review of approved protocols, Completion/ Final reports & Translated versions of Informed consent forms.**
Quorum	**Number of IEC members required to act on any motion presented to the Board for action.**

Scientists	**Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed**
SOP historical files	**A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all pre-planned deviations.**
SOP Team	**A selected committee of the members of ICMR-NIRRCH Ethics Committee who oversee the creation, preparation, review and periodic revision of the institute's SOPs.**
SOP (Standard Operating Procedure)	**Detailed, written instructions, in a certain format, describe all activities and actions undertaken by an organization to achieve uniformity in the performance of a specific function.** **The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.**
Strategies to Manage Conflict of Interest	1. **Disclose conflict of interest** 2. **Document the conflict of interest in the attendance register and minutes of the meeting** 3. **Refrain from taking part in any discussion/review/ debate about the proposal;** 4. **Refrain from participating in the review process of the project proposal by leaving the meeting room.**
Study Assessment Form	**An official record that documents the protocol review process.**
Vulnerability	**The Council for International Organizations of Medical Sciences (CIOMS) defines vulnerability as persons who are vulnerable because they are relatively (or absolutely) incapable of protecting their interests.**

Vulnerable (research) participants	**Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (WHO)**
Workshop	**A group of people engaged in study or work on a creative project or subject**

Institutional Ethics Committee

ICMR – National Institute for Research in Reproductive & Child Health

(SOPs, IEC)

Codes: 01 / V1.6, 02 / V1.5, 03 / V1.3, 04 / V1.2, 05 / V1.2, 06 /V2.2, 07 / V1.5, 08 / V1.4, 09 / V1.7, 10 / V1.1, 11 / V3.4, 12 /V2.1, 13 / V1.4, 14 / V1.4, 15 / V1.5, 16 / V1.4, 17 / V1.4, 18 /V1.5, 19 / V1.4, 20 / V1.3, 21 / V1.5, 22 / V1.5, 23 / V1.2, 24 /V1.2, 25 / V1.2, 26 / V1.2, 27 / V1.1

Prepared by SOP Team:

Name and Position on the IEC	Signature with date
Dr. Vikrant Bhor **Member Secretary**	8/11/2024
Dr. Bhakti Pathak **Joint Member Secretary**	8/11/2024
Dr. Sandeep Bavdekar **EC Member (Non- Affiliated)**	Bavdekar 8/11/2024
Dr. Rakhi Tripathi **EC Member (Non- Affiliated)**	8/11/2024

Members of the Institutional Ethics Committee:

Sr.No	Name	Qualification with Specialization	Current Organization	Designation / Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1.	Dr. Shubhada Chiplunkar	MSc, Ph.D, (Cancer Research)	Former Director ACTREC-TMC Kharghar Navi Mumbai	Chairperson	Non - Affiliated
2.	Dr. Vikrant Bhor	MSc Life Science, Ph.D	Scientist-E Head of Department (Molecular Immunology Microbiology) ICMR – National Institute for Research in Reproductive and Child Health J. M. street Parel Mumbai -12	Member Secretary Basic Scientist	Affiliated
3	Dr. Bhakti Pathak	MSc, Ph.D (Life Sciences)	Scientist-F Head of Department (Cellular and Structural Biology Division) ICMR – National institute for Research in Reproductive Child Health J. M. street Parel Mumbai -12	Joint Member Secretary Basic Scientist	Affiliated
4.	Dr. Yogeshwar Nandanwar	MBBS, M.D. Obstetrics and Gynecology	Professor (Obstetrics and Gynecology) D.Y. Patil Medical College & Research Centre , Mumbai	Clinician	Non - Affiliated
5.	Dr. Sandeep Bavdekar	MBBS, MD Diploma in Child Health, Certificate in Hospital & Health Care Management	Ex-Professor & Head Pediatrics Department, BYL Nair Charitable Hospital & T.N Medical College Mumbai	Pediatrician	Non - Affiliated
6.	Dr. Sivakami Muthusamy	Ph.D and Population Studies	Professor & Chairperson. Center for Health and Social Sciences. School of Health System Studies. Tata Institute of Social Sciences, V.N. Purav Marg. Deonar Mumbai -400088	Social Scientist	Non - Affiliated
7.	Dr. Ketki Kulkarni	MBBS, M.D. Obstetrics and Gynecology	Ex - Assistant Professor in OB GY, Nowrosjee Wadia Maternity Hospital, Mumbai Consultant Obstetrician and Gynecologist and Foetal Medicine Specialist.	Clinician	Non - Affiliated
8.	Dr. Rakhi Tripathi	MBBS, MD (Pharmacology)	Associate Professor Dept of pharmacology & Therapeutics Seth G.S. Medical College & KEM hospital, Parel, Mumbai-12	Pharmacology Expert	Non - Affiliated

9.	Dr. Bipin Kulkarni	MSc Life Science, Ph.D	Scientist-E Head, Department of Hemostasis and Thrombosis ICMR-NIIH, Mumbai-12	Basic Scientist	Non - Affiliated
10.	Mrs. Sudha Sathaye	B. com Bussiness Graduation by Goldman Sach	Sole Proprietorship Bussiness	Community Person	Non - Affiliated
11.	Dr. K.V. Ganpathy	Masters In Human Resourse Management, TISS Ph.D (MSW)	Chief Executive Officer (Jeet Association for Support to Cancer Patients)	Community Person	Non - Affiliated
12.	Adv. Ajay Shinde	BSc (Chemistry), D.Pharm, LL.B	Independent Lawyer	Legal Expert	Non – Affiliated
13.	Dr. Shailesh Pande	MBBS, MS (Anatomy)	Scientist-E Head of Department (Genetic Research Centre) ICMR – National institute for Research in Reproductive Child Health J. M. street Parel Mumbai -12	Clinician	Affiliated
14	Dr. Sadhana Gupta	MSc, Ph.D (Life Sciences)	Scientist-D Head of Department (Infectious Disease) ICMR – National institute for Research in Reproductive Child Health J. M. street Parel Mumbai -12	Basic Scientist	Affiliated

Approved By:

Name and Position on the IEC	Signature with date
Prof. Shubhada Chiplunkar (Chairperson, IEC)	ICMR-National Institute For Research In Reproductive And Child Health ★ Ethics Committee For Human Studies ★ CHAIRPERSON

Accepted by:

Name and Position on the IEC	Signature with date
Dr. Geetanjali Sachdeva, Director, ICMR – NIRRCH	8/11/2024 डॉ. गीतांजलि सचदेवा/Dr. Geetanjali Sachdeva निदेशक/Director आई.सी.एम.आर-राष्ट्रीय प्रजनन एवं बाल स्वास्थ्य अनुसंधान संस्थान ICMR-National Institute for Research in Reproductive and Child Health जहांगिर मेरवानजी पथ,/Jehangir Merwanji Street, परेल, मुंबई 400012/Parel, Mumbai-400 012 ICMR-NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE AND CHILD HEALTH J. M. STREET, PAREL MUMBAI - 400 012.