TRICHY SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE

Irungalur, Tiruchirapalli

[Affiliated to The Tamilnadu Dr. M.G.R. Medical University, Chennai]

INSTITUTIONAL RESEARCH BOARD (IRB)

Handbook of Research Code of Ethics

[SOP for Institutional Ethics Committee]

(Uncontrolled Copy)

Institutional Research Board
III Floor, College Block
(0431-2258691/ 2258817)
researchcmchrc@gmail.com

Date of preparation: 18.06.2020
Date of verification: 20.06.2020
Date of Approval: 20.06.2020
Date of Implementation: 20.06.2020
Next Review Date: 30.12.2020

Prepared by	Verified by	Approved by
Dr. N. Prabhusaran	Dr. SD. Nalinakumari	Dr. N. Balasubramanian
Coordinator – IEC	Member Secretary – IEC	Dean & Licensed Authority - IEC

Contents

Code No.	Index	Page No.
1	Preface	1
2	General Ethical Principle	2
3	Mandate	3
4	Purpose	4
5	Scope	4
6	Organogram	4
7	Responsibility	5
8	Copies of SOP	6
9	Request for formulation of new SOP/ Revision of SOP	8
10	Composition of IEC	9
11	Frequency of meetings	18
12	Quorum requirements	19
13	Education for IEC members	19
14	Honorarium for external members	20
15	Report of plagiarism	20
16	Collaborative Research	20
17	Types of decisions by IEC	22
18	Informed consent process	22
19	Ethical meetings in unusual periods (Emergency Research Review)	28
20	Documents to be maintained by IEC	28
21	Certification	29
22	Annual Activity Report	29
23	General Code of Ethics	30
Annexures		
1	Proforma for Institutional Research Board (IRB) Approval for IEC clearance	
2	Consent form in English	
3	Consent form in Vernacular language (Tamil)	

Trichy SRM Medical College Hospital and Research Centre
Irungalur, Tiruchirapalli – 621 105

[Affiliated to the Tamilnadu Dr. M.G.R. Medical University, Chennai]

Document No.: IRB – IEC – 01

Department: Institutional Research Board (IRB)

Title of the SOP: Research Code of Ethics and SOP for Institutional Ethics Committee (IEC)

Supersedes: New

Date of preparation: 18.06.2020

Date of verification: 20.06.2020

Date of Approval: 20.06.2020

Date of Implementation: 20.06.2020

Next Review Date: 30.12.2020

1.0. Preface

The Institutional Ethics Committee (IEC) established in 2010 is responsible for the scientific, ethical and regulatory oversight of research conducted at Trichy SRM Medical College Hospital and Research Centre (TSRMMCH&RC), and serves to protect the rights and welfare of human subjects.

Standard Operating Procedures (SOPs) of IEC provide guidance to the members of IEC, research scholars and other stake holders involved in research. Adherence to these guidelines would help to promote and maintain the standards towards ethical conduct of research, and protect the rights and wellbeing of research participants and communities.

Various national and international bodies have developed and promulgated guidance documents for the ethical conduct of clinical research. The cornerstone of these ethical guidelines is that research should be subject to prior ethical review by a competent Institutional Ethics Committee. The present SOPs draw reference to these guidelines and documents and have been framed considering the variability in expertise, experience, training and capacity of IEC members at TSRMMCH&RC.

A set of SOPs have been developed to maintain consistency in the process of review and continuous monitoring of research proposals by the IEC. This SOP has been made to adhere strictly for the conduct of medical research involving human participants as well as identifiable human materials and data. All future revisions of the IEC SOPs will be made to reflect the changes in the national laws and guidelines and to keep pace with the international advances in the field of bioethics.

The ultimate mandate of these SOPs will be to further the cause of conduct and adherence to the highest standards of human research.

2.0. General Ethical Principles

- All research with human participants is presumptively subject to IRB oversight. Specific categories of research may be exempted from IEC review or subject to expedited and full committee review as per this SOP guideline.
- IEC is part of larger research participant protection programmes that also include training for IEC members and researchers, and mechanisms to ensure that IECs work efficiently and effectively.
- Procedures exist to ensure clear and efficient communication, harmonization of standards, networking and cooperation among other research committees and between different levels of committees, as applicable. These procedures enable IEC to learn about prior decisions by other committee that may be relevant to the proposed research under review. In addition, procedures exist for the coordinated review of multi-site research, whether regionally or in more than one centers.
- Mechanisms exist to ensure that IEC's activities are coordinated with national regulatory authorities' oversight of drugs, biologics, and medical devices, as well as with national and/or international clinical trial registries
- Mechanisms are in place for obtaining community input into the ethics review system.

This research code of ethics consists of four principles including respect for the rights and dignity of the person; competence, responsibility and integrity.

3.0. Mandate

The IEC of TSRMMCH&RC is an autonomy body of the institution under the guidance of the Head of the Institution maintaining a consistent scientific and ethical framework for patient care and research, and for integrating ethical values into practice, policy relationships and organizational activities.

The purpose of the IEC is to cultivate a pluralistic and democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of the Institution.

The mandate of the IEC essentially is to promote patient care through a scientific and ethical approach to research and education.

The terms of reference for the IEC are as follows:

- Ensure the highest scientific and ethical standards of research at TSRMMCH&RC
- Review and approve proposals for basic, clinical and translational research projects (Intra and Extra mural) for scientific and ethical content.
- Improve ethical standards and issue guidelines on ethical dilemmas related to patient care services.
- To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public.
- To endeavor to be a national standard of reference
- To issue and periodically, update and revise SOPs and guidelines for effective functioning of IECs as and when necessary.
- Continuing the education in clinical research and bioethics by holding seminars, workshops and interactive discussions for all categories of students, research scholars, staff members including nursing and paramedical staff.
- To initiate and commission research studies on ethical aspects of practice in TSRMMCH&RC

The IEC endeavors to provide guidance on a broad range of topics such as disclosures of diagnosis, diagnosis of brain death, indications for stopping resuscitation, true informed consent etc. The committee does not address or interfere in matters of administration of the institution, nor does the committee function as a grievance cell for staff members.

4.0. Purpose

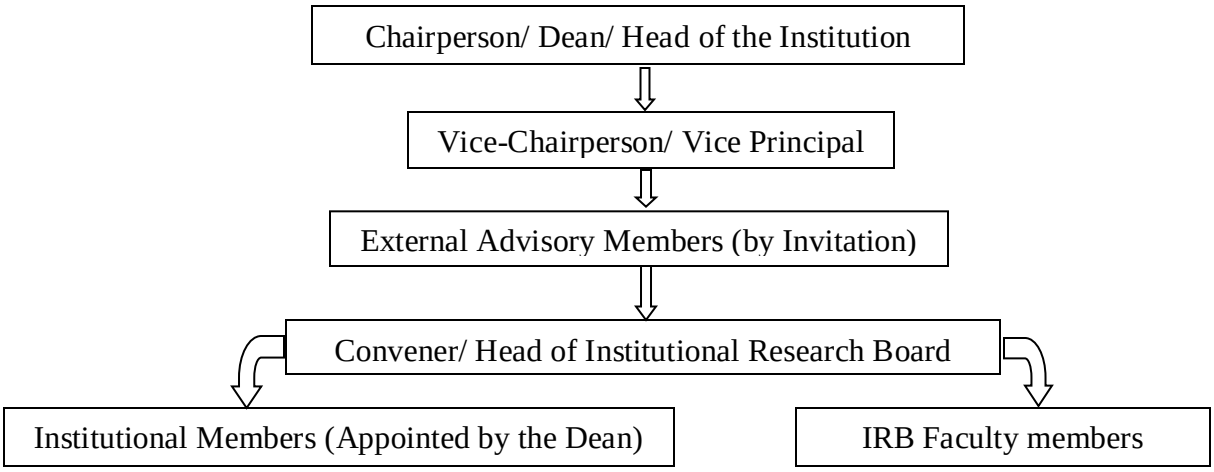
This SOP defines the process for writing, reviewing, distributing, and amending research procedures within the IEC, TSRMMCH&RC. The SOP also defines procedures for documentation, archival, retrieval, destruction of SOP to ensure that the latest SOPs are followed. The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines 2019.

5.0. Scope

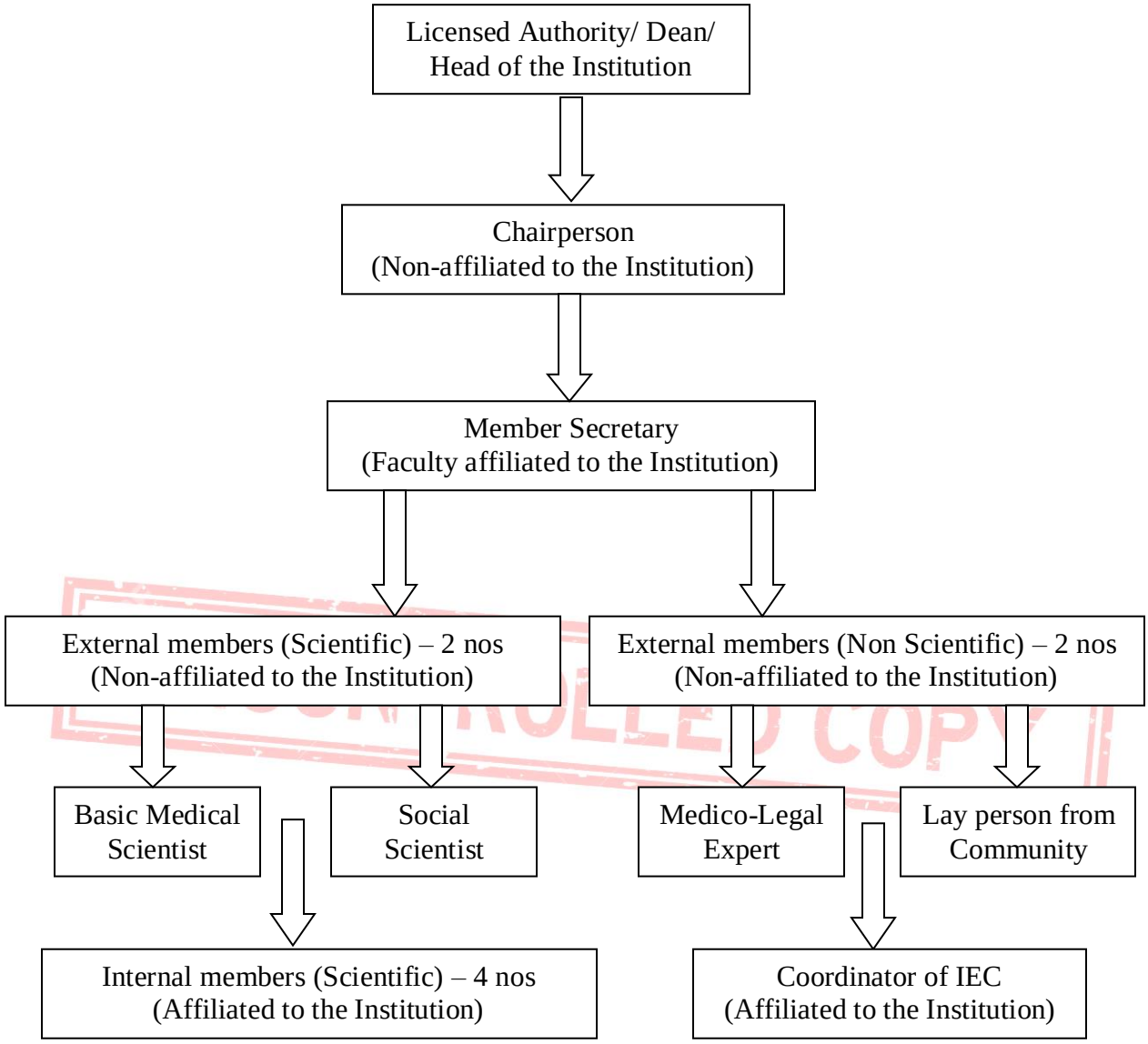
This SOP covers the procedures of writing, reviewing, distributing, and amending research procedures within the IEC, TSRMMCH&RC and to define control of SOP documents at the IEC

6.0. Organogram of Institutional Research Board (IRB) and Institutional Ethics Committee (IEC)

6.1. Organogram of Institutional Research Board (IRB)



6.2. Organogram of Institutional Ethics Committee (IEC)



7.0.<u>Responsibility</u>

It is the responsibility of the Chairperson of the IEC to appoint the SOP Team to formulate the SOPs. SOP team will prepare the draft of SOPs. The draft SOPs will be reviewed and approved by the IEC members. SOP team will be responsible to amend the SOPs as and when required. It is the responsibility of the IEC Member Secretary and staff for maintaining control on all the SOPs.

The IEC Coordinator is responsible for ensuring that the current approved version of the SOP is available on the institutional website. The SOP will bear the effective date and validity.

The IEC Coordinator will notify all concerned user via email of document updates (recent version). For the user, electronic access will be limited to a read-only format, thereby protecting against unauthorized changes made to the document.

When SOPs are revised, the IEC Coordinator will inform the networking department to remove obsolete copies from the institutional website and upload the current approved version of the SOP.

SOPs will be reviewed by the members of IECs. The Chairpersons of IECs will approve the SOPs. The SOPs will then be signed by the Dean, TSRMMCH&RC as these are Institutional Ethics Committees for Research Review.

SOP team will consist of Member Secretary of IEC, Coordinator, administrative staff and one or two IEC members. The team will

- Assess the request(s) for SOP revision in consultation with the Chairperson
- Propose a new, or modification in existing SOPs as needed
- Select the format and coding system for the SOPs
- Draft the SOP
- Review the draft SOP
- Submit the draft for approval to the Chairperson

7.1. IEC members

- Review, sign and date SOPs
- Return all out-of date SOPs to IEC office (IRB of TSRMMCH&RC)

7.2. Coordinator of IEC

- Co-ordinates activities of writing, reviewing, distributing, and amending SOPs.
- Maintains on file all current SOPs and the list of SOPs.
- Maintain a file of all SOP amendment requests
- Maintains an up-to-date distribution list of each SOP circulated to IEC members

- Maintain a record of the investigators to whom SOPs are distributed against a requisition
- Ensures that all IEC members and involved administrative staff have access to the SOPs
- Ensures that the IEC members and involved staff are working according to current version of SOPs
- Maintain a file of all previous SOPs of the IEC
- Assist in the formulation of SOP procedure
- Ensure SOP revisions as and when required to comply with national regulations

8.0. Copies of SOP

The IEC Coordinator will prepare the master copy/ controlled copy/ uncontrolled copy. The issuance of controlled and uncontrolled copies will be with the permission of the Member Secretary.

Standard Operating Protocol for IEC		
Master copy	**Controlled copy**	**Uncontrolled copy**
➢ Approved original copy of documents and will have a stamp/watermark of "Master copy". ➢ Master copy shall be kept in the IEC office with access control. ➢ Signature in all pages is mandatory	➢ Copy of the master copy with a stamp/ watermark of "Controlled copy". ➢ Controlled copies shall be kept in the IEC with access control. ➢ Controlled copy is a reference copy of master copy for the IEC members and IEC staff. ➢ Five hard copies will be maintained in the IEC office ➢ This copy will be circulated to all IEC members ➢ Counter signature is mandatory	➢ Copy of master copy with a stamp/watermark of "Uncontrolled copy". ➢ Uncontrolled copies shall be kept in the IEC with access control. ➢ Uncontrolled copy is a reference copy of the master copy for the users such as researchers/ research staff, sponsor, regulators and any other stake holders in research

Note: All these data will be maintained as Archives and only the uncontrolled copies shall be distributed upon request. The issuance log of uncontrolled copies will be maintained.

9.0. Request for Formulation of new SOP/ Revision of SOP

This form is to be completed and submitted to the Member Secretary by any IEC member/ Coordinator whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place. Finally the Coordinator or the Member Secretary will present this issue in the IEC meeting as "Full Committee Review"

SOP No.	
Title of the SOP	
Details of problems or deficiency in the existing SOP	
Indentified by:	Date
Discussed in IEC meeting held on	
References to be modified or clarified	
Points to be revised	
Date SOP revised	
Date of SOP approved	
Date of SOP become effective	

All the Research proposals which would be primarily/ completely carried out in TSRMMCH&RC or with collaboration with the national front institutions and research centres will be reviewed by the Institutional Ethics Committee of TSRMMCH&RC. Primarily all the Research proposals will be subjected to the Institutional Research Board (IRB) of TSRMMCH&RC for preliminary evaluation and eligible proposals would be transferred to IEC.

Name and Address of the IEC of TSRMMCH&RC

Institutional Ethics Committee (IEC), Institutional Research Board (IRB),
Trichy SRM Medical College Hospital and Research Centre
Irugalur Post, Manachanallur Taluk, Tiruchirapalli – 621 105, Tamilnadu
Phone: +91-431-2258691/ 2258817; Email: researchcmchrc@gmail.com

The Institutional Ethics Committees (IEC) of TSRMMCH&RC is constituted by the Dean, TSRMMCH&RC under the authority vested by the Management of TSRMMCH&RC. The head of the Institute (HoI) who serves as appellate has the power to dissolve the IEC or reappoint the IEC.

10.0. Composition of IEC

- IEC will be multidisciplinary and multi-sectorial in composition with members of adequate age and both gender.
- IEC is composed of a minimum of 7, and maximum of 15 members. The members are selected so as to have an equitable representation of all specialties. It includes scientific and non-scientific members, clinicians and non - clinicians, a clinical pharmacologist, members of the community, a lawyer-expert in ethics, a social worker/ layperson/ patient representative to represent different points of view.
- The Committees will comprise of Chairperson, Member Secretary, Coordinator and other active members who represent an appropriate balance of professional, ethical, legal, cultural, educational and community interests.
- As far as possible, based on the requirement of research area such as oncology, HIV, genetic disorder, specific patient group (Cancer survivor), or NGO's representatives may also be represented in the Ethics Committee (as special invitee).
- The Committee should have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community / society.
- Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by TSRMMCH&RC.

The composition of IEC should be as follows:-

1. Chairperson (non-affiliated to TSRMMCH&RC)
2. Member secretary (TSRMMCH&RC faculty member)
3. One or Two External members (non-affiliated to TSRMMCH&RC)
4. Four Internal members (TSRMMCH&RC faculty members)
5. Basic medical scientist (External/ Internal)
6. Clinical Pharmacologist (Internal)
7. One legal expert or medico-legal expert (Internal/ External)
8. One social scientist / representative of non-governmental voluntary agency/ philosopher / ethicist / theologian (External)
9. One lay person from the community (non-affiliated to TSRMMCH&RC)
10. Institutional Coordinator (affiliated to IRB of TSRMMCH&RC)

10.1. Membership

The Dean (Head of the Institution), TSRMMCH&RC appoints the Chairperson and the Member Secretary of the IEC. All IEC members will be appointed by the Dean, TSRMMCH&RC in consultation with the Chairperson and Member Secretary of the IEC. The Dean is the licensing authority and he/ she shall be informed in writing about the constitution of the Ethics Committee or in case of any change in the membership.

10.2. Criteria for selection of members

- It is the duty of the member secretary of the IEC in consultation with the Chairperson of IEC to select the new or additional members.
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile, and research experiences.
- The members representing medical scientist and clinicians should have post graduate qualification and adequate experience in their respective fields.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
- Dean, Head of Institution, Medical Superintendent, Vice Principal, Administrative officers and other ex-officio members who are responsible for business development at TSRMMCH&RC will not serve as members.
- The member secretary of IEC is eligible to propose the addition and modification of the IEC committee by submitting a proposal to the head of the Institution with the new members' detailed biodata and justification.
- The official appointment order has to be issued to all the members by the Head of the Institution and their written consent, joining report and detailed biodata will be obtained. All should be documented as Controlled copy in the office of IEC.

The following qualities are sought in IEC members

- ❖ experience and education
- ❖ research interest and motivation
- ❖ commitment and availability
- ❖ respect for divergent opinions
- ❖ integrity and diplomacy

10.3. Terms of Appointment

10.3.1. Duration

- ➢ The Chairperson, Member Secretary, Coordinator and members of the IEC, TSRMMCH&RC will be appointed for duration of 3 years.
- ➢ The appointment procedure for membership will be followed so that it allows for continuity, development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches.
- ➢ The members can be continued and there will be no limit on the number of times the membership is extended. Extension of membership will be based on the recommendation of the Chairperson and Member Secretary of the IECs.
- ➢ To ensure that the quorum requirement is met during the IEC meetings, if the members is not participating in two consequent meetings means, then member Secretary report the same to the Head of the Institution through Chairperson IEC for replacing new member for the place. This is applicable for Chairperson, Member Secretary and Coordinator also. No substitution will be permitted for the members. The IEC meeting minutes will document presence and absence of the members and the attendance should be countersigned by the member Secretary.
- ➢ In case of the resignation/ discontinuation of the Member Secretary, Chairperson or member, a replacement will be appointed by the Dean, TSRMMCH&RC before the completion of the tenure of the existing appointed committee. This appointment will be effective for the remaining tenure of the existing Committee.

10.3.2. Renewal

- The membership will be renewed after the stated term of 3 years based on the recommendation of the Member secretary.
- The process of renewal will be as follows
  - Selection of Chairperson, Member Secretary and other members should be done at least 3 months in advance. Member secretary designate should be inducted into the IEC as an observer before he/ she takes on the mantle in the new IEC. Other member designates may attend the board meeting as observers before starting their tenure as IEC members
  - If a regular member resigns, or ceases to be a member due to disqualification or death, a new member will be appointed for the remaining term as per the conditions of appointment

10.3.3. Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the Dean, TSRMMCH&RC. IEC members who decide to resign must provide a letter to the member Secretary by written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Dean, TSRMMCH&RC would appoint a new member, falling in the same category of membership e.g. social scientist with social scientist. Recommendations may be sought from the resigning member. Appointments may be made in consultation with the Member Secretary and /or Chairperson.

10.3.4. Termination / Disqualification procedure

- A member may be relieved or terminated of his/ her membership in case of
- Conduct unbecoming of a member of the IEC
- Inability to participate in the meetings on any grounds
- Failure to attend 2 and more consecutive meetings of the IEC without prior intimation and subsequent review of the membership by the IEC; if deemed necessary, the IEC may decide to relieve the membership. Chairperson, IEC may make a recommendation to the Dean, TSRMMCH&RC for necessary action.

- In all such circumstances, Dean, TSRMMCH&RC will re-constitute IEC membership roster and the same will be circulated.

10.3.5. Conditions of Appointment

- Name, gender, profession and affiliation of IEC members will be publicized.
- Members must accept the appointment in writing. The appointment letter issued to all members should specify the Terms of Reference (TOR). The letter issued by the head of the institution should include, at the minimum, the following:
  - Role and responsibility of the member in the committee
  - Duration of appointment
  - Conditions of appointment
- Members must submit a one page current CV along with their acceptance letter
- Conflict of interest, if any, must be disclosed.
- Members must apprise themselves to the guidelines of ICMR and IEC of TSRMMCH&RC.
- Financial interests that require disclosure include but are not limited to:- Ownership interest, stock options, or other economic interest related to the research, Board, scientific officer, or executive relationship related to the research and regardless of compensation for that position.
- Non-financial interests that require disclosure include but are not limited to:- Participation in the research project as key personnel (PI, Co-PI, sub-investigator), Co-Author on a publication of the research project's results and Other relationships which may influence judgment of the IEC member in reviewing the research project
- An investigator can be a member of the IEC. However, the investigator-as-member cannot participate in the review and approval presentation; but the co-investigator is allowed to present the proposal without disclosing the name of the PI (member of IEC) as this may give potential conflict of interest or a request is made to leave that particular IEC member from the forum during their proposal presentation.

10.3.6. Roles and Responsibilities

10.3.6.1. Chairperson

- The IEC Chairperson should be a highly respected individual from outside TSRMMCH&RC, fully capable of managing the IEC and the matters brought before it, with fairness and impartiality.
- The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of Chairperson.
- The IEC must be perceived to be fair and impartial, immune from pressure of TSRMMCH&RC's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources.
- The IEC Chairperson will respect the diverse backgrounds, perspectives and sources of expertise of all IEC members, especially the contributions of the non-scientists, and must have the ability to foster respect among the IEC members.
- The Chairperson shall ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical members) in all discussions and deliberations.
- The Chairperson shall ratify minutes of the previous meetings, handle complaints against researchers and IEC members, conflict of interest issues and requests for use of IEC data, assessing the validity of the IEC certificates and follow ups.

10.3.6.2. Member Secretary

- The Member Secretary will be a staff member of TSRMMCH&RC, committed to the task of coordinating and managing the activities of the committee.
- He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.
- Specific roles of Member Secretary (As per ICMR Guidelines 2017)
    - Member Secretary will be responsible for ensure training of IEC Coordinator and IEC members
    - Ensure SOPs are updated as and when required

- ❖ Ensure adherence of IEC functioning to the SOPs
- ❖ Prepare for and respond to audits and inspections
- ❖ Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review.
- ❖ Assess the need for expedited review/ exemption from review or full review

The Member Secretary/ Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full committee review.

a. ***Exempted from Review (A)*** – proposals with less than minimal risk like data from public domain; review papers; meta-analysis; observation of public behavior; quality control and assurance audits, instructional techniques; consumer acceptance studies; questionnaires and evaluation of public health programmes; these types of projects are not necessary to present in the IEC meeting; but the full details of the projects should be kept in the IEC meeting for getting oral approval for issuing the IEC certificates.

b. ***Expedited Review (B)*** – proposals no more than minimal risk like non-identifiable specimen, human tissues and samples from laboratory, blood bank and left over clinical samples; clinical documentation materials; modification of approved protocol; change in researchers for the approved projects; revised protocols and research of emergencies and disasters; the presentation status of these types of projects will be decided by the IEC committee on the date of IEC meeting; but the full details of the projects should be kept in the IEC meeting for getting oral approval for issuing the IEC certificates.

c. ***Full Committee Review (C)*** – proposals of more than minimal risk like inclusion of vulnerable population, invasive procedures, certain sensitive questionnaires; deception of participants; major changes and modifications of the existing protocols and research of emergencies and disasters; All these group of projects are mandatory to present in front of the IEC committee and reviewed. All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting

10.3.6.3. IEC Coordinator

The Coordinator (affiliated to IRB) is appointed by the Head of the institution, TSRMMCH&RC. The main responsibilities of the Coordinator are

- Review of new research applications for consistency, completeness and compliance with the regulations and institutional guidelines prior to convene IEC review
- Providing necessary administrative support for IEC related activities
- Organizing IEC meetings regularly
- Preparing the agenda and drafting minutes of the meetings
- Organizing an effective and efficient tracking procedure for each proposal received
- Updation of the IRB software system and the IEC online portal
- Preparing, maintaining and distributing study files
- Supervision of the maintenance, archival and shredding of the study files
- Corresponding with the IEC members, external experts and investigators on all IEC related matters
- Arranging training for study personnel and IEC members
- Supervision of the pre and post arrangements of IEC meetings
- Answering queries of the investigators
- Supervision of filing of study related documents.
- Quality check of all study related documents submitted to IEC as well as correspondence from IEC.
- Preparation for accreditation and audits
- Organizing training for investigators, key study personnel, IEC members and IEC staff
- Participating in the development and subsequent implementation of SOPs
- Participating in, or presenting, research related education sessions
- Initiating research studies in ethics/audits
- Drafting letters, receipt, vouchers etc
- Meeting attendance preparation/ preparation of dispatch folders.

10.3.6.4. Attendants /Helpers

- Assisting the coordinator in arranging the IEC meetings.
- Dispatching sets of study documents to IEC members and external experts.
- Receiving the study related documents from and dispatching the IEC letters to the investigators.
- Filing study related documents.
- Archiving and maintaining the study files
- Shredding of the closed files as per SOP

10.3.6.5. IEC members

- The members' primary responsibilities will be to determine the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research participants.
- Participate in the IEC meeting.
- Review and discuss research proposals and other documents pertaining to the study.
- Submit assessment forms to the IEC Coordinator individually with signature and date.
- Review progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- The IEC member shall evaluate whether a conflict of interest exists, and he/she shall disclose any identified conflicts to the IEC at the next IEC meeting.
- Carry out work delegated by the Chairperson and/or Member Secretary.
- Participate in continuing education activities in bio-ethics and biomedical research.
- Provide information and documents related to training obtained in bio-ethics and biomedical research to the IEC Member secretary, periodically.

10.3.6.6. Specific roles of the members

10.3.6.6.1. Clinician - Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics; Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report); Review medical care, facility and appropriateness of the principal investigator, provision

for medical care, management and compensation and thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

10.3.6.6.2. Basic Medical Scientist - Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, protocol deviation, progress and completion report.

10.3.6.6.3. Clinical Pharmacologist - Clinical trials, pharmacologist to review the drug safety and pharmacodynamics and assessing drug activities, and targets.

10.3.6.6.4. Legal experts - Ethical review of the proposal, International Classification of Diseases (ICD) along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, compliance with guidelines etc. Interpret and inform IEC members about new regulations.

10.3.6.6.5. Social Scientists/ Philosopher/ Ethicist/ Theologian - Ethical review of the proposal, ICD along with the translations; Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any; Serve as a patient/ participant/ societal / community representative and bring in ethical and societal concerns.

10.3.6.6.6. Layperson - Ethical reviews of the proposal, ICD along with translation(s); Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks; Serve as a patient/participant/ community representative and bring in ethical and societal concerns;

In the absence of the Chairperson, any one of the external member who is independent of the institution will chair the meeting as the acting Chairperson with the written permission of Chairperson.

11.0. Frequency of meetings

The IEC meetings are scheduled at regular intervals or on ad-hoc basis. In out Institution, the IEC meetings will be planned quarterly (minimum three per year), depends on the number of protocols to be reviewed.

12.0. Quorum Requirements

All research projects for approval by the full board of the IEC shall be reviewed at convened meetings at which a majority of the members of the IEC will be present. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The presence of the 60% of the members (excluding member secretary) is required to form part of the quorum without which a meeting cannot be convened and a decision regarding the project cannot be taken. These 60% members should have the following representation

1. Chairperson/ Represented member
2. One of the external member apart from Chairperson
3. Basic scientist
4. Clinician
5. Social scientist
6. Legal expert
7. Lay person

13.0. Education for IEC Members

IEC members have a need for initial and continued education regarding the science and ethics of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines. IEC members will receive introductory training material in IEC SOPs and research bioethics and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.

The IEC members should undergo initial and continuing training in human research protection, applicable to IEC SOPs and related regulatory requirements. All trainings should be documented and chance given by rotation basis.

The Member Secretary in consultation with the Chairperson shall prepare an annual activity report of the IEC for submission to the Head of the Institution, TSRMMCH&RC for any accreditation agencies and the same has to be updated in the institutional website. This shall include:

- Quantitative evaluation of the activities of the committee in a year.
- List of the research proposals reviewed in a year

- Follow ups and ongoing projects
- Status of the completed projects

14.0. Honorarium for external members

The TA and sitting fees for the external members will be paid as per the establishments registered with CPCSEA (Ref. F.No.25/28/2017 – CPCSEA dt. 22.04.2019). The sitting fees for the external members and TA is given as per the ICMR guidelines.

15.0. Report of plagiarism

The report related to the following may be discussed in the IEC forum. The complaint related to plagiarism, fabrication and falsification of the research works should be submitted to the Member Secretary for taking necessary action.

- Fabrication is the intentional act of making-up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment or processes, or changing or omitting/suppressing data or results without scientific or statistical justification, such that the research is not accurately represented in the research record.
- Plagiarism is the "wrongful appropriation" and "stealing and publication" of another paper or another author's "language, thoughts, ideas, or expressions" and the representation of them as one's own original work or duplicating one's own publication (self plagiarism).

16.0. Collaborative research

Researchers are increasingly collaborating with colleagues who have the expertise and/or for resources needed to carry out particular research. This could be inter-departmental/ inter-institutional or international and also multicentre involving public and/or private research centres and agencies.

The main ethical issues surrounding collaborations pertain to sharing techniques, ownership of materials and data, IPRs, joint publications, managing research fundings, managing conflict of interest and commercializing research outcomes.

Researchers should familiarize themselves with all aspects including local, national and international requirements for research collaboration including necessary approvals, memorandums of understanding (MoUs) and material transfer agreements (MTA) and IEC approval of collaborating institutes.

16.1. Ethical considerations in collaborative research

- Collaborative studies should take into account the values/benefits expected from the research as compared to the risks involving the persons/population being studied.
- The participating centres should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR as appropriate. There must be free flow of knowledge and capacity at bilateral/multilateral levels.
- Careful consideration should be given to protecting the dignity, rights, safety and well-being of the participants in cases where the social contexts of the proposed research can create foreseeable conditions for their exploitation or increase their vulnerability to harm.
- The nature, magnitude and probability of all foreseeable harm resulting from participation in a collaborative research programme should be specified in the research protocol and well explained to the participants.
- The benefits and burdens should be equally distributed amongst participants recruited by all collaborating institutions.
- All participants in collaborative research should have access to the best nationally available standard of care.
- If there is exchange of biological material involved between collaborating sites, the IEC may require appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

17.0. Types of decisions by IEC

An IEC can give one of the following decisions

17.1. Approved – with or without suggestions or comments;

17.2. Revision with minor modifications/ amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;

17.3. Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or

17.4. Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.

18.0. Informed Consent process

The researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants. This requirement is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research. Informed consent is a continuous process involving three main components – providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual's freedom of choice and respects the individual's autonomy.

18.1. Types of Consent

18.1.1. ***Verbal/oral consent:*** For research on sensitive topics, verbal/oral consent or pseudonyms may be suitable with appropriate approval of the EC and with proper documentation.

18.1.2. ***Broad consent:*** Providing an individual opt-out option, consultation may be held with only a small representative group of the population of interest.

18.1.3. ***Group consent:*** Cluster randomized trials (CRT), IR, and demonstration projects are examples where IECs have to decide on the complex issues of feasibility and type of consent to be obtained from the participants.

An informed consent form must include the following:

- Statement mentioning that it is research
- Statement mentioning that the data will be published
- Purpose and methods of the research in simple language
- Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods
- Benefits to the participant, community or others that might reasonably be expected as an outcome of research
- Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study
- Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality
- Payment/reimbursement for participation and incidental expenses depending on the type of study
- Free treatment &/or compensation of participants for research-related injury and/ or harm
- Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled
- The identity of the research team and contact persons with addresses and phone numbers (for example, PI/Co PI for queries related to the research and Chairperson/ Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)

The IEC may grant consent waiver in the following situations:

- research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/ data from medical records;
- certain types of public health studies/ surveillance programmes/programme evaluation studies;

- research on data available in the public domain; or
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

18.2. Consent from Child participants

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ guardians.

18.3. Assent

In addition to consent from parents/Guardians verbal/oral or written assent, as approved by the IEC, should be obtained from children of 7–18 years of age. As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures, that the child understands the request to participate in the research. A child's agreement to participate in research is called assent. If the child objects, this wish has to be respected.

18.4. Public Health Research Reviews

When reviewing public health research proposals, IECs should consider the followings aspects:

- Are the objectives of the study scientifically sound and linked to the achievement of public health goals?
- Is individual written informed consent required?
    - If not, is gatekeeper consent/permission sufficient? Who is a gatekeeper and how is this decided?
    - Is it a two-stage process – initially a gatekeeper consent/permission followed by individual consent?
- If applicable, is respect for the community applied through community engagement? If so, is the methodology appropriate?

- Which segments of the population are likely beneficiaries and what are the expected benefits?
- Is individual harm overriding the potentially larger societal benefit?
    - If so, is it justified?
    - What are the different types of potential harm?
    - Who would be harmed?
    - What, if any, measures can be taken to mitigate/minimize this?
    - How do societal benefits outweigh individual harm?
- Is social justice considered while designing, implementing and assessing outcomes of the study?

18.5. Consent in public health research may be waived

- On routinely collected data under programme conditions, including research involving linkage to large anonymous databases of information that has been routinely collected such as administrative data and through surveillance activities. However, at the time of collection people concerned may have been told that the data would be used for other purposes, including research;
- in circumstances where obtaining consent is impractical, such as for stored anonymous data/ biological samples, surveillance and administrative data or personal non-identifiable data/ material available from public health programmes;
- for studies performed within the scope of regulatory and public health authorities, such as process and impact evaluations of national policies and programmes, including neonatal screening programmes or diabetes screening as part of national programme activities may be exempt from the requirement for informed consent;
- when the primary purpose is refinement and improvement of the public health programmes; for studies using health-related registries that are authorized under national regulations; or
- When it is not practical or meaningful to obtain consent in large geographical clusters in cluster randomization trials.

18.6. Biological samples

Biological materials or biospecimens or samples include biological fluids, such as blood, dried blood spots, body fluids, urine, tissues, organs, cord blood, oocytes, sperm, semen or embryos. These may be stored or prospectively collected. Informed consent, confidentiality, privacy and re-consent are largely influenced by the degree of identifiability, whether the biospecimens and data are anonymized or not. As a general principle, research must be conducted on least identifiable data.

18.6.1. Types of samples

18.6.1.1. Anonymous/ Unidentified: No identifiers are present from the start or if collected, are not maintained. Such samples are received by biobanks without any identifiers and supplied to researchers.

18.6.1.2. Anonymized: This involves systematic de-identification, reversible or irreversible: link of samples/data to personal identity is reversibly or irreversibly cut.

18.6.1.2.1. ***Coded or reversibly anonymized:*** There is an indirect link of sample/ data to the participant's identity with restricted access. This link could be re-linked if required; therefore, it may also be termed reversible anonymization.

18.6.1.2.2. ***Irreversibly anonymized:*** Link to the participant's identity is removed and cannot be re-linked.

18.6.1.3. Identifiable: A direct link of sample/data to the participant's identity exists.

18.6.2. Types of Consent and its implications in specific to clinical specimens

18.6.2.1. Blanket or broad consent: This is an open consent given only once to collect the sample, store it and use it for any research at any time in future without the need to revert to the individual for a re-consent. A consent model that allows for current and future access and use of samples or data for research without necessarily specifying what the focus of such studies might be used.

18.6.2.2. Tiered consent: This model of consent offers several options from which participants can choose. It includes an opt-in option for future use specifying general permission, or use only related to some aspects of research, sharing of biospecimens/ data benefit sharing, etc. It also takes into consideration return of results for which options are also provided for consent.

18.6.2.3. Specific consent: Consent is obtained for a specific research purpose. Participants are recontacted for every new use of their stored samples/data if the scope of research is outside that for which they had originally given consent.

18.6.2.4. Delayed consent: It may be administered in the post-medical procedure period when biospecimen or data may be collected for appropriate research from critically ill patients who may not have given prior consent for research. Consent may be taken from the participant or attender when it is practical.

18.6.2.5. Dynamic consent: This consent is different from one of static, paper-based consent and involves an ongoing engagement and interactions over time with participants to re-contact in response to changing circumstances using technology based platforms. It incorporates a flexible, configurable, technology-based design accommodating both participant and researcher needs. Modern longitudinal biobanks equipped with advanced technology strive for this type of consent.

18.6.2.6. Withdrawal of consent or destruction of sample: The donor has the right to ask for destruction of his/ her collected sample(s) and discontinuation/withdrawal from participation in the research. In longitudinal studies, a participant may withdraw from one component of the study, like continued follow-up/data collection when withdrawal may be referred to as partial.

18.6.2.7. Waiver of consent: While using anonymized (de-identified) samples/data, researchers should seek the approval of the IEC of the institution or the repository for waiver of consent from donors.

18.7. Re-consent

18.7.1. Secondary or extended uses of stored samples/dataset: In such an instance, one of the preliminary considerations for IECs must be to identify the circumstances under which the research requires re-use of collected identifiable biological material to generate the data or utilize the pre-existing identifiable dataset.

This must also include review of the informed consent obtained originally to see if re-consent is warranted. There may be situations where consent would be impossible or impracticable to obtain for such research, in which case the research may be done only after independent evaluation by an IEC.

18.7.2. Pediatric donors: In longitudinal studies once the child donor attains the legal age of consent a re-consent should be sought for the storage and use of her/his tissue or sample. In pediatric biobanks or biobanks with pediatric samples it is important to address the issue of children reaching legal age of consent. Sometimes re-contact may lead to withdrawal, resulting in limited data analysis. This may lead to bias or it could evoke emotional distress about past research. On the other hand, re-consent may give the participant the power to agree. A biobank should decide the policy it would like to adopt for re-contact.

19.0. Ethical meetings in unusual periods - Emergency Research review

Virtual or Tele/ Video conferences should be attempted to ensure the strict adherence of guidelines like social distancing as face-to face meetings may not be suitable and the meeting could be digitally recorded (audio/ video) with permission of members.

There are 3 categories of research during unusual periods that may require ethics review

1. New research directly related to particular unusual situations (eg. Research related to COVID)
2. Ongoing non-unusual research
3. New non-unusual research

The IEC must prioritize research review based on urgency and take needful steps to facilitate the review of new research and conduct ongoing research with needful amendments as per need in the view of guidelines, policies etc. (eg. hand sanitizing, social distancing etc).

20.0. Documents to be maintained by IEC

20.1. *Administrative documents*

- Constitution and composition of the IEC
- Appointment letters
- Signed and dated copies of the most recent curriculum vitae of all IEC members
- Training records of IEC members
- Financial records of IEC
- Registration/ accreditation documents, as required
- A copy of national and international guidelines and applicable regulations
- Regulatory notifications
- Meeting-related documents with circular, agenda, attendance, comments and minutes
- All communications received or made by the IEC
- SOPs

20.2. *Proposals related documents*

- One hard copy and a soft copy of the initial research proposal and all related documents
- Decision letters
- Any amendments submitted for review and approval
- Regulatory approvals
- Protocol deviations/ violations
- Progress reports, continuing review activities, site monitoring reports
- All correspondence between the IEC and researchers
- Final report of the study
- Record of notification issued for premature termination of a study with a summary of the reasons
- Follow up status report
- Publications made through IEC certified projects

21.0. Certification

A Decision of the IEC will be communicated to the applicant immediately. A certificate of the approval will be sent to the applicant within one week. All the IEC certificates should have the validity period (double of the study period stated by the research scholar). Quarterly review should be done to assess the status of the research work. The researcher should carry out the project within the stipulated period and if extension needed, she/ he have to submit a request letter for the extension to Member Secretary, IEC through proper channel.

22.0. Annual Activity Report

The IEC Coordinator in Consultation with the Member Secretary and Chairperson shall prepare an annual activity report of the IEC for submission to the Head of the Institution and accreditation agencies. This shall include:

- A quantitative evaluation of the activities of the Committee in a year including timely completion of the research, extension details and outcome of the research
- List of the research proposals reviewed in a year

****

23.0. General Code of Ethics (As per ICMR guidelines)

Essentiality: whereby the research entailing the use of human participants is considered to be absolutely essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research

Voluntaries, Informed Consent, Community Agreement: whereby research participants are fully apprised of the research and the impact and risk of such research on the research participant and others

Non-exploitation: whereby as a general rule, research participants are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research participants kept fully apprised of all the dangers arising in and out of the research

Privacy and Confidentiality: whereby the identity and records of the human participants of the research or experiment are as far as possible kept confidential

Precaution and Risk Minimization: whereby due care and caution is taken at all stages of the research and experiment

Professional Competence: whereby the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality

Accountability and Transparency: whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research

Maximization of Public Interest and Distributive Justice: whereby the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind

Institutional Arrangements: whereby there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required

Public Domain: whereby the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known

Totality of Responsibility: whereby the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions lay down generally or in respect of the research or experiment

Compliance: whereby, there is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human participant to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guideline.

Ref: https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf

****

Prepared by	Verified by	Approved by
Dr. N. Prabhusaran	Dr. SD. Nalinakumari	Dr. N. Balasubramanian
Coordinator – IEC	Member Secretary – IEC	Dean & Licensed Authority – IEC