Institutional Ethics Committee
Mahatma Gandhi Medical College & Hospital
RIICO Institutional Area, Sitapura, Tonk Road, JAIPUR - 302 022 (Raj.) INDIA
Phone : 0141-2770677, 2770798, 2771777, 2771001 – 3 Fax : 0141-2770677
Website : www.mgmch.org ; email : mgumst.ethics.committee@gmail.com

Effective from: 18/04/2022

Standard Operating Procedure
Human Institutional Ethics Committee
Mahatma Gandhi Medical College and Hospitals
Jaipur -302022

- IEC as per Central Drugs Standard Control Organisation (CDSCO) Ministry of Health and Family Welfare, Government of India, New Delhi Registration No: ECR/125/Inst/RJ/2013/RR-19, Valid till 19th April, 2024
- IEC for Biomedical and Health Research as per National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) Provisional registration No: EC/NEW/INST/2019/402, Valid till-27th may,2022

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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Document in supersession of earlier versions-

Prepared By:

S. No.	Name and Position on HIEC	Signature with Date
1	Dr. R. K. Sureka, Member Secretary	RK Sureka

Member Secretary, IEC
MGMC, JAIPUR

Member Secretary, IEC
MGMC, JAIPUR

Approved By:

S. No.	Name and Position on HIEC	Signature with Date
1	Dr. S. C. Lodha, Chairperson	

Chairman
Institutional Ethics Committee
MGMC, Jaipur

Accepted By:

S. No.	Name and Position on HIEC	Signature with Date
1	Dr. Swati Garg, Principal & Controller	

Principal & Controller
Mahatma Gandhi Medical College & Hospital
Sitapura, JAIPUR

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Reviewed By:

S. No.	Name and Position on HIEC	Signature with Date
1	**Dr. R. C. Gupta**, Clinician	
2	**Dr. Puneet Rijhwani**, Clinician	
3	**Dr. Munish Kumar Kakkar**, Clinician	
4	**Dr. Amitabh Dube**, Basic Scientist	
5	**Dr. Monica Jain**, Basic Scientist	
6	**Smt. Preeti Soni**, Lay Person	Preeti Soni
7	**Dr. Mani Sachdev**, Philosopher	
8	**Mr. Siddhant Jain**, Legal Expert	

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16.0 Annexure

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Ethics Committee Requirements Details

S. No.	Requirements	Remarks
1	*Number of Members in Ethics Committee (EC)*	**15**
2	*Ethics Committee* Meeting Frequency	**Once in 6-8 Weeks**
3	*Ethics Committee Fees*	**Processing fee of Rs 60,000, amendment fee- Rs. 25,000 per amendment, archival fee- Rs. 10,000, annual review fee Rs. 30,000 for budget Rs. <10 lakh & Rs. 45,000 for budget Rs. >10 lakh.**
4	Drawee Name for *Ethics Committee Fees*	**Mahatma Gandhi university of medical sciences and technology, Jaipur**
5	*Number of sets of Ethics Committee Submission*	**15**
6	*Time Required for Ethics Committee Approval Letter*	**10 to 15 days**
7	*Deadline for Submission*	**Three weeks prior**
8	*Language Required for Informed Consent*	**English and Hindi**
9	*Documents Required by Ethics Committee*	**Protocol with Amendments, Investigator's Brochure (IB), Informed Consent Form (ICF) [Hindi and English], Clinical Trial Agreement (CTA), Investigator Undertaking, Insurance Certificate, etc. (as per SOP)**

Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur-302022.

Professor (Dr.) R. K. Sureka
Member Secretary

Signatory of SOP approval
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1.0 Introduction and Authority

This *Ethics Committee* functions as *Institutional Ethics Committee*, hereafter referred to as **Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur-302022** for *Human Research, Jaipur*. It is under the authority of **The Principal and Controller,** *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* with address as *RIICO Industrial Area, Sitapura, Jaipur-302022 (Phone no. +91-141-2771002,1800-180-6002; email id:* mgumst.ethics.committee@gmail.com*).*

The following Standard Operating Procedure (SOP) is based upon the current *Indian Guidelines [New Drugs & Clinical Trials Rules, 2019 of Central Drugs Standard Control Organisation (CDSCO), Drugs Controller General of India (DCGI), Ministry of Health, Government of India, New Delhi, National Ethical Guidelines of Indian Council of Medical Research (ICMR), 2017]*, and *Good Clinical Practice Guidelines* issued by *International Conference on Harmonisation-Good Clinical Practices (ICH-GCP) Guidelines.*

This SOP establishes the authority of the **Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur-302022** for *Human Research*, to review pharmaceutical and epidemiological clinical research and trial projects. All pharmaceutical and epidemiological clinical trial projects must be submitted to the **Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur-302022** for *Human Research for review and approval before commencement of the trial and/or research project.*

The *Institutional Ethics Committee* of *Mahatma Gandhi Medical College and Hospitals, Jaipur-302022* will serve to protect the *dignity, rights and well-being* of *participating subjects/ patients and affiliated Consultants/ Specialists/Faculty Members at Mahatma Gandhi Medical College and Hospital, Jaipur-302022* to conduct the clinical research at the Institution itself only.

2.0 General

All research projects that are designed and envisaged to be undertaken at the *Institution Site of Mahatma Gandhi Medical College and Hospitals, Jaipur-302022* need to be necessarily sent to *Institutional Ethics Committee (IEC) [after being assessed by the Departmental Research Committee]*. All postgraduate M.D./M.S. dissertations plans are assessed and sieved through *Institutional Research Review Board (IRRB)* and an *IEC* review sought when needed. All self-

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initiated research projects inclusive of doctoral studies would be processed through *DRC* and *IEC*. A written approval is essential before the commencement of the research project. All project proposals are sent to the *Member Secretary* of the *Ethics Committee* at least three weeks prior to the forthcoming scheduled *EC Meeting*.

2.1 Management and Maintenance of Standard Operating Procedure (SOP)

It is the responsibility of **The Chairperson** of the *IEC* to appoint an *SOP Team* to formulate the *SOP*. The *SOP Team*, comprising of *Member Secretary* and five or six other *Members of the IEC*, drafts the *SOP*, gets it reviewed and approved by all *IEC Members* and amends it as and when required. All members of the *IEC* will review the *SOP* and approval will be given by **The Chairperson** of the *IEC*. The *SOP* will be accepted by **The Principal and Controller, Mahatma Gandhi Medical College and Hospital, Jaipur-302022.**

Secretariat of Institutional Ethics Committee (IEC)

- Coordinates activity of writing, reviewing, distributing and amending *SOPs*.
- Maintains on file all current *SOPs* and the list of *SOPs*.
- 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 all *IEC Members* and involved administrative staff have access to the *SOPs*.
- Ensures the *IEC Members* and involved staff are working according to current version of *SOPs*.
- Maintain a file of all past *SOPs* of the *IEC*.
- Assist in the formulation of *SOP* procedure.

2.2 Writing, Reviewing, Distributing and Amending Standard Operating Procedure (SOP)

Any member of the *Institutional Ethics Committee (IEC)*, secretariat or administrative staff or investigators, can make a request or revision or notices an inconsistency / discrepancy / has any suggestions on how to improve the existing *SOPs* or requests to design an entirely new *SOP* can put forth his request by using the *Request Form* for *Formulation of New SOP / Revision of an SOP Form* to make a request **(Annexure 16.38).** This form is submitted to the **Chairperson**. The **Chairperson** will Inform all *IEC Members* about this request in a regular full board meeting.

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If *IEC Members* agree to the request, the **Chairperson** will appoint an appropriate *SOP Team* that will proceed with the task of *revision/formulation* of the *SOP*.

The *SOP Team* will assess the request for *SOP revision* in consultation with *Secretariat* and **Chairperson**, propose new/modified *SOPs* as needed, select the format and coding system and draft, review and submit the *Draft SOP* for *Approval* to the **Chairperson**.

If the *IEC Members* do not agree to the request, no further action will be taken.
The **Chairperson** will inform the person/*IEC Member* who made the request for modification of the *SOP* in writing about the decision.

If *IEC Members* agreed on the request, then the *SOP* will be prepared by the *SOP Team*, *draft SOP* will be discussed during respective *IEC meeting*, *Members* can put forth their suggestions / comments on the *draft / revised SOP*. The *suggestions* agreed upon unanimously by all *IEC Members* will be incorporated and the *Final Draft SOP* will be formulated. The *SOP Team* would stand automatically dissolved once the *IEC* take final decision regarding the *SOP*.

The *Final Version* will be forwarded to the **Chairperson** for review and approval. The **Chairperson** will sign and validate and date the *SOP*. The date of approval is declared as the *Effective Date* of implementing the *SOP*. The approved *SOP* will then be submitted to **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospitals, Jaipur-302022* for acceptance.

Once the *Final Version of SOP* is authenticated and dated by the **Chairperson**, *IEC* and **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022*, all pages of the *SOP* should be signed by *Member Secretary*.

The *Approved SOP* will be distributed to all *IEC Members* and old version will be retrieved from all members and destroyed. A copy of the *old version* will be archived in a master file.

Photocopies made from these official paper versions of *SOP* can be considered current official, if stamped and signed by *Member Secretary* or *authorised personnel* for distribution, a log of which should be maintained.

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
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MGMC, Jaipur

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2.3 Validity

The *Current Approved SOP* is valid for *three years* from the date it was approved and became operational. It will be amended with necessary changes as and when required, accordingly.

3.0 Constitution of Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur-302022.

The *Institutional Ethics Committee (IEC)* will be *multidisciplinary* and *multi-sectorial* in composition and will have a minimum of 7 and maximum of 15 members. The members are selected to have an equitable representation of all specialties from the Institution inclusive of *scientific and non-scientific, clinicians and non-clinicians, clinical pharmacologist, members of the community, legal experts in ethics, social worker/lay person/patient representative to represent different point of view* with respect to research on human subject/participants. The Institute has two *scientific committees* namely, *Departmental Research Committee (DRC)*, that reviews scientific essence, viability and relevance of research project and after due critical sieving and analysis in terms of science and value added advantage of the research design in contemporary times, the *DRC* forwards the research projects to *Institutional Ethics Committee* for the needful.

3. 1 Membership Requirements and Secretariat

This *Institutional Ethics Committee* comprises of members from various backgrounds in order to promote and evolve a complete, fair, transparent and objective review of *Biomedical Research Projects* proposed to be conducted at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022*. There will be representations from both genders in the *Committee* and the constituent members will have adequate qualification, experience and expertise in their respective fields. It will also comprise of members who will be competent enough to ascertain the fulfilment of the applicable commitments and policies of hospitals, applicable regulatory guidelines and standards of professional conduct and practice.

Criteria for Selection of Institutional Ethics Committee Members

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile.
- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regards to such interests.

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- New members will be identified according to requirement.

The following qualities are sought in the IEC members:

- *Interest and Motivation.*
- *Time and Effort.*
- *Commitment and Availability.*
- *Experience and Education.*
- *Respect for Divergent Opinions.*
- *Integrity and Diplomacy.*

The *Ethics Committee, Mahatma Gandhi Medical College & Hospitals, Jaipur-302022* consisting of following members has been constituted by letter no. No./MGMCH/Est./2022/18815 dated 12th April 2022.

S. No.	Name (with Qualifications)	Designation	Affiliation
1	**Dr. S. C. Lodha**, Retired Professor, General Surgery, Jaipur	**Chairman**	**Non-Affiliate**
2	**Dr. R. K. Sureka**, PHOD, Department of Neurology, MGMC, Jaipur.	**Member Secretary**	**Affiliate**
3	**Dr. R. C. Gupta**, Professor, Department of Anesthesiology, MGMCH, Jaipur.	**Member (Clinician)**	**Affiliate**
4	**Dr. Puneet Rijhwani**, PHOD, Department of General Medicine, MGMCH, Jaipur.	**Member (Clinician)**	**Affiliate**
5	**Dr. Monica Jain**, Professor, Pharmacology, SMSMCH, Jaipur.	**Member (Basic Medical Scientist)**	**Non-Affiliate**
6	**Dr. Rajaat Vohara**, PHOD, Community Medicine, MGMCH, Jaipur.	**Member (Basic Medical Scientist)**	**Affiliate**
7	**Dr. Amitabh Dube**, Professor, Physiology, SMSMCH, Jaipur.	**Member (Basic Medical Scientist)**	**Non-Affiliate**
8	**Dr. Munish Kumar Kakkar**, PHOD, Pediatric Medicine, MGMCH, Jaipur.	**Member (Clinician)**	**Affiliate**
9	**Dr. Anusha Vohara**, Professor, Pharmacology, MGMCH, Jaipur.	**Member (Basic Medical Scientist)**	**Affiliate**
10	**Mr. Anubhav Chandel**, Advocate, Hon'ble Rajasthan High Court, Jaipur Bench, Jaipur.	**Member (Legal Expert)**	**Non-Affiliate**

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11	**Mr. Siddhant Jain**, Advocate, Hon'ble Rajasthan High Court, Jaipur Bench, Jaipur.	**Member (Legal Expert)**	**Non-Affiliate**
12	**Ms. Vani Tiwari**, Masters in Sociology	**Member (Social Scientist)**	**Non-Affiliate**
13	**Dr. Mani Sachdev**, Professor Philosophy, Manipal University, Jaipur.	**Member (Philosopher)**	**Non-Affiliate**
14	**Smt. Preeti Soni**, Lay Person from Community, Jaipur.	**Member (Lay Person)**	**Non-Affiliate**
15	**Dr. (Mrs.) Lata Joshi**, Lay Person from Community, Jaipur.	**Member (Lay Person)**	**Non-Affiliate**

The Chief Account Officer/Representative will be an invited member.

- It is encouraged to invite *Non-Member Experts* for opinion on specific indication (*Non-Member experts will not be allowed to vote*).
- A list of members, their qualification and affiliation is maintained by the *IEC*. A copy of the *IEC* composition and operating procedure can be made available to any member of the Institute for filing of research projects, upon written request for the same to the *IEC*.

IEC Office Bearers

The *Ethics Committee* of *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* will have following *Office Bearers*, having requisite expertise and professional qualification to evaluate and review research projects on human participants/subjects:

The Chairperson

The *IEC* **Chairperson** is from outside the Institute, capable of managing the *IEC* and the matters brought before it with objectivity, transparency and impartiality. The task of making the *IEC* a respected part of the Institutional Community is of primal importance and is the primary responsibility of the **Chairperson**. The *IEC* must be perceived as fair and impartial, immune to pressure either by the Institution's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources.
The **Chairperson** will conduct all meetings of the *IEC* and if the **Chairperson** is not available, for reasons beyond control, an *Alternate Chairperson* will be selected by the members present from amongst themselves.

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Member Secretary

The **Member Secretary** is a faculty member of the Institute, responsible for coordinating and managing the activities of the *Committee* including scheduling of the meetings, descriptive preparation of agenda and ensuring that the function of the *Committee* is conducted as per *norms and policies laid down in this SOP.*
In absence of **Member Secretary**, for reasons unfathomable and beyond control, a faculty member of *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* may perform the function the **Member Secretary**, if deemed necessary.

Detail of Supporting Staff

The staff is appointed and posted at *IEC* to maintain all documents, files and computer work logistics.

The Secretariat shall have following functions:

- Organising an effective and efficient tracking procedure for each protocol received.
- Preparation, maintenance and distribution of study files.
- Organising *IEC Meetings* on a regular basis.
- Preparation of agenda and minutes of the meetings.
- Maintaining *IEC documents* and *archives*.
- Communicating with *IEC Members* and respective *Principal Investigators (PIs)*.
- Arrangement of training for personnel and *IEC Members*.
- Providing necessary administrative support for *IEC related activities* to the *Member Secretary, IEC*.
- To receive *IEC Official Fees receipt and file*, accordingly.

The IEC Administrative Staff: Working Rules

1. There will be administrative officer/s and attendant/s/helper/s who will help the **Chairperson** and **Member Secretary** in executing functions of the *IEC*. Additional staff may be appointed and duties assigned as and when deemed necessary by the *IEC*. The eligibility criteria for new staff to be appointed will be laid down depending on the requirements of the job profile as per laid down norms of the Institute. The need for appointment of administrative staff, job profile

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and qualifications may be recommended by the *IEC Members* during regular *IEC Meetings* and will be recorded in the minutes, that would be forwarded to **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospitals Jaipur-302022* for the needful.

2. The administrative staff will be appointed as per the process and norms observed by the Institute.

Duties of Administrative Staff

- Correspondence with *IEC Members* and *External Experts*.
- Correspondence with the *Investigators*.
- Pre and post arrangements of *IEC Meetings*.
- Preparation of agenda and minutes of *IEC Meetings*.
- Answering queries of the *Investigators*.
- Filing of study related documents.
- Archiving and maintaining study files.

Duties of Attendant/s/Helper/s

- Assisting the secretariat 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.
- Correspondence with *IEC Members* and *External Experts*.

3. The administrative staff will report to the **Chairperson** and/or **Member Secretary**
4. The Office timing for the administrative staff will as per *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* rules and regulations.
5. The administrative staff will avail leave as norms of the Institute, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022*.

Roles and Responsibilities of IEC Members

- The *Committee's* primal responsibilities will be protection of safety, rights and confidentiality of the research subjects/participants.

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- Active Participation in *IEC Meetings*.
- Review and discuss research proposals submitted for evaluation.
- Review progress reports and monitor ongoing studies.
- Monitor *Serious Adverse Events (SAEs)* and recommend appropriate measures and actions as per norms.
- Maintain confidentiality of the documents and deliberations of *IEC Meetings*.
- Declare *Conflict of Interests (COI)*, if any.
- To carry out work delegated by **Chairperson** and **Member Secretary**.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to *IEC Secretariat*.

Decision Making

- Decision is arrived at by consensus; however, if consensus not possible, then voting is carried out.
- Opinions of absent members that are transmitted by mail or telephone or fax may be considered by attending members during discussion.
- Any *Committee Member* with conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the *Committee*. Such abstentions will be recorded in the minutes. Decision is arrived at by consensus; however, if consensus not possible, then voting is carried out.

3.2 Quorum

The **Mahatma Gandhi Medical College and Hospitals Institutional Ethics Committee (IEC)** is the highest body of the Institute and in keeping with the goal of imparting value-added and quality medical education and patient care, *research* happens to be the *a priori* of the Institution. Research is an integral part of the mission and mission of *MGMCH* and is oriented and directed towards areas of evolving needs with specific import on application of transforming knowledge to relevant pressing medical issues. The inculcation of an attitude of inquiry, acquisition of knowledge of mechanistic of research methodologies with execution of research at various levels of involvement in health care are encouraged in faculty and students. Research relevant to State's and Nation's need is incentivised and inspired through both intramural and extramural funding mechanisms.

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The **Member Secretary** ensures that at least a quorum of *5 Members* is present at each review meeting as per *New Drugs and Clinical Trials Rules (NDCT) Rules, 2019* of *Central Drugs Standard Control Organisation (CDSCO), Drugs Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017*, in order to provide collective expertise ensuring a comprehensive review, inclusive of both *scientific and ethical*, of the projects submitted to it.

The *Institutional Ethics Committee (IEC)* shall evaluate Scientific, Academic, Relevance and Ethical aspects of all clinical drug trials / projects /research works proposed to be conducted at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* and grant approval/disapproval for the same as per provisions contained in *New Drugs and Clinical Trials Rules, 2019 and Drugs & Cosmetics Act, 1940 & Rules 1945 of Central Drugs Standard Control Organisation (CDSCO), Drugs Controller General of India (DCGI), Ministry of Health, Government of India, New Delhi, National Ethical Guidelines of Indian Council of Medical Research (ICMR), 2017*, and *Good Clinical Practice Guidelines* issued by *International Conference on Harmonisation-Good Clinical Practices (ICH-GCP) Guidelines.*

The ethical principles that guide contemporary research in human participants stem from guidance from various organisations through the travails and tyranny of times that humankind has witnessed and include the *Nuremberg Code of 1947* that was aptly backed by *Universal Declaration of Human Rights (adopted by the General Assembly of the United Nations) in 1948.* "*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*" of 1978, submitted by *US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research* sets forth basic ethical principles underlying acceptable conduct of research involving human participants that respect autonomy of persons, beneficence, non-malfeasance and justice, which incidentally are the quintessential requirements for ethical conduct of research involving human participants. The related guidelines of *International Guidelines for Ethical Review in Epidemiological Studies (1991)*', '*International Ethical Guidelines for Biomedical Research involving Human Subjects*' of *Council for International Organisations of Medical Sciences (CIOMS)* and *World Health Organisation (WHO) (1993 revised in 2002)*], *Nuffield Council Guidelines (2002)* focus on observance of ethical norms relevant to the protection of research participants in the pluralistic cultural environments. Many national and regional bioethics advisory bodies that are updated or added to, periodically.

The *Indian Council of Medical Research (ICMR)* brought out the revised guidelines in a continuum in 2017 as the '*National Ethical Guidelines for Biomedical and Health Research*

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Involving Human Participants'(*https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf*).

The Ministry of Health and Family Welfare, Government of India body, Central Drugs Standard Control Organisation (CDSCO), Drugs Controller General of India (DCGI) lay down mandatory stipulations and guidelines relating to research on human participants involving new drugs, new innovative medical devices and surgical interventions inclusive of instrumentation and diagnostics. The Indian Good Clinical Practice (GCP) guidelines (http://www.cdsco.nic.in/html/GCP1.html) lay down more detailed guidance on the conduct of clinical trials. In addition the *New Drugs and Clinical Trials Rules, 2019* lays down (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf) rules and regulations to clinical drug trials involving human subjects.

Regulations for export of biological materials are laid down by the *Director General of Foreign Trade* (http://dgftcom.nic.in) and material transfer agreement of the *ICMR*. For clinical trials, permission for shipment of biological materials to overseas central laboratories may be included in the approval from *Drugs Controller General of India*. All internationally funded research needs approval by *Health Ministry's Screening Committee (HMSC)*; this is to screen such research for potential violations of national security and intellectual property rights.

As per *ICH (International Conference on Harmonisation), CDSCO, Indian and ICMR Guidelines* on *GCP (Good Clinical Practices)*, the following criteria should be fulfilled in order to obtain a *quorum* and consist of at least one representative from the following groups:

1. *One Basic Medical Scientist (preferably One Pharmacologist).*
2. *One Clinician.*
3. *One Legal Expert or Retired Judge.*
4. *One Social Scientist/Representative of Non-Governmental Organisation [NGO]/Philosopher/Ethicist/Theologian or a similar person.*
5. *One Lay Person from the Community*

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Composition, Affiliations, Qualifications, Member Specific Roles and Responsibilities of Ethics Committee

S. No.	Member Specific	Definition/Description
1	Chairperson	· Conduct EC Meetings and Accountable to Independent and Efficient Functioning of Committee. · Ensure Active Participation of All Members, inclusive of Non-Affiliate, Non-Medical, Non-Technical, in all discussions and deliberations. · Ratify minutes of previous meetings. · In case of absence of Chairperson at scheduled EC meeting, the Chairperson will nominate a committee member as *Acting Chairperson* on the day of meeting. The *Acting Chairperson* shall be *non-affiliated Committee Member* and will have all powers of *Chairperson* for that meeting. · Seek *Conflict of Interest (COI)* from members and ensure *quorum and fair objective decision making.* · Handle complaints against *Researchers, EC Members, Conflict of Interest (COI) issues, requests for use of EC data and other related and miscellaneous issues.*
2	Member Secretary/ Alternate Secretary *Affiliated Member* Qualifications: · Faculty member of the Institute. · Should have knowledge and experience in clinical research and ethics, motivated, sensitive and have good communication skills · Should be able to devote adequate time to this activity which should be protected by the Institution	· Organise effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review. · Schedule EC meetings, prepare agenda and minutes. · Organise EC documentation, communication and archiving. · Ensure training of EC secretariat and EC members. · Ensure *SOPs* are updated as and when required. · Ensure adherence of *EC functioning to the SOPs.* · Prepare for and respond to *audits* and *inspections.* · Ensure completeness of documentation at time of receipt and timely inclusion in agenda for EC review. · Assess need for expedited review/exemption from review for full review. · Assess need to obtain prior scientific review, invite independent consultant, patient or community representatives. · Ensure quorum during meetings and record discussions and decisions.

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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3	**Basic Medical Scientist(s)** *Affiliated/Non-Affiliated* Qualifications: · Medical person with qualifications in *Basic Medical Sciences.* · In case of *EC* reviewing clinical trials with drugs, *Basic Medical Scientist* should preferably be a *Pharmacologist*	· Scientific and ethical review with special emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report. · For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4	**Clinician(s) Affiliated/Non-Affiliated Qualifications:** **· Should be individual(s) with recognised medical qualification, expertise and training**	· Scientific review of protocols inclusive of review of intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. · Ongoing review of protocol (SAE, Protocol Deviation or Violation, Progress and Completion Report). · Review Medical Care, Facility and Appropriateness of Principal Investigator, Provision for Medical Care, Management and Compensation. · Through Review of Protocol, Investigators Brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal Experts Affiliates/Non-Affiliated Qualifications:** **· Should have basic degree in Law from recognised University with experience.** **· Desirable: Training in Medical Law.**	· Ethical review of Proposals, Information Consent Document (ICD) along with translations, Memorandum of Understanding (MOU), Clinical Trial Agreement (CTA), Regulatory Approval, Insurance Document, Other Sites Approval, Researcher's Undertaking, Protocol Specific Other Permissions such as Stem Cell Committee for Stem Cell Cell Research, Health Ministry's Screening Committee [HSMC, Government of India] for International Collaboration, Compliance with guidelines and other related and miscellaneous issues. · Interpret and inform EC members about new regulations, if any.

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6	**Lay Person(s) Non-Affiliated Qualifications:** · **Literate person from Public/Community** · **Has not pursued a Medical Science/Health-related career in last 5 years.** · **May be representative of community from which participants are to be drawn.** · **Is aware of local language, cultural and moral values of community.** · **Desirable: involved in social and community welfare activities.**	· Ethical review of Proposals, ICD along with translation(s). · Evaluate benefits and risks from participant's perspective and opine whether benefits justify risks. · Serve as a patient/participant/community representative and bring in ethical and societal concerns. · Assess on societal aspects, if any.
7	**Social Scientist / Philosopher/Ethicist/ Theologian** **Affiliated/Non-Affiliated Qualifications:** · **An individual with social/ behavioral science/ philosophy/religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from NGO involved in health-related activities**	· Ethical review of the proposal, Informed Consent Document along with 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.

3.2.1 Terms of Appointment (Reference)

3.2.1.1 Duration of Appointment and Conditions:

The members of *IEC* of *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* are appointed for a duration of 3 years.

The members are continued and there is no limit on the number of times the membership is extended. Extension of membership is decided by **The Principal and Controller,** *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* in consultation with the **Chairperson.** The appointment of **Member Secretary, Chairperson** or **Member**, when newly appointed during and

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before the completion of the tenure of existing *Committee* will be effective for remaining tenure of existing members.

3.2.1.2 Renewal of Appointment

The membership will be renewed after the stated term of 3 years.

The process of renewal will be as follows: *Selection of Member Secretary and Other Members should be done 6 months and 3 months in advance, respectively. Member Secretary* designate should be inducted in the *Committee* as a *Member* before he/she takes on the mantle in the new *IEC*. Other members designate may attend the *Committee Meeting* as *Observers*, before taking on the charge and tenure of *IEC Member*.

Designated *Members* of the *IEC* who wish to attend *IEC Meetings* as *Observes* should read, understand, accept and sign the confidentiality documents in the *Confidentiality / Conflict of Interest* at the beginning of the *IEC Meeting* and/or before ethical review tasks of the *IEC* commence.

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* stated below (**3.2.1.5**).

3.2.1.3 Resignation/Replacement Procedure

The members who have resigned shall be replaced by the appointing authority, **The Principal and Controller, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022***. The *IEC Member* who decides to resign should send a written notification of resignation to **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* at least 15 days before the date of resignation so submitted. **The Principal and Controller,** *MGMCH, Jaipur* would appoint a new member, falling in the same category of membership in consultation with the **Chairperson**. Similarly, if internal faculty members proceed on leave for more than 6 months, **The Principal and Controller**, *MGMCH, Jaipur* may replace with another faculty member in consultation with **Chairperson**.

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3.2.1.4 Removal/Termination/Disqualification Procedure

A member may be relieved or terminated of membership in case of:

- *Conduct unbecoming for a Member of the Ethics Committee.*
- *Inability to participate in the meetings.*
- *If a member fails to attend more than 3 consecutive meeting of IEC, the matter shall be reviewed by the IEC. If deemed necessary, the IEC may decide to terminate the membership and recommend to* **The Principal and Controller**, *MGMCH, Jaipur, through* **Chairperson** *IEC for necessary replacement.*

In all such situation/circumstances, **The Principal and Controller,** *MGMCH, Jaipur* will send a letter of termination to the *Member*. Documentation of termination will be record in the meeting minutes of the next forthcoming scheduled duly constituted *IEC Meeting* and *IEC Membership circular/roster will be revised.*

3.2.1.5 Conditions of Appointment

- Name, age, gender, profession and affiliation of *IEC Member* will be publicized.
- Members must accept appointment in writing.
- Conflict of interest, if any, must be disclosed.
- Members must approve themselves of the relevant documents, *New Drugs and Clinical Drugs Trials (NDCT) Rules, 2019 of CDSCO, DCGI, ICH-GCP, ICMR guidelines and IEC, Mahatma Gandhi Medical College & Hospital, Jaipur SOP. Members are required to sign and validate the Confidentiality Agreement.*
- The *Confidentiality Agreement* protects the privacy and confidentiality of all parties whose information may be disclosed to the *IEC* in course of its work.
- Any *Investigator* can be a *Member of IEC*; however, the *Investigator-as-Member* cannot participate in the review and approval process for any project in which the *Member* is *PI, Co-PI* or has any other potential *conflict of interest*.

3.2.1.6 Terms of Independent Consultants

The *IEC* may call upon *Independent Consultants and/or Faculty Members of the Institute* who may provide expert and specialist opinion on a subject as and when required by the *IEC* on submitted *proposed research projects*, when the **Chairperson** or the *IEC Members* determine that a research

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study will involve procedures or information that are not within the domain and area of expertise the *IEC Members*. These *Specialists/Consultants* may be experts in *ethical or legal aspects, specific disease or methodologies (e.g., genetic disorders, stem cell research, etc.)* or they may be representatives of communities, patients or special interest groups. These *Consultants* must sign and validate *Confidentiality Document/Agreement* regarding meeting, deliberations and related matters. These consultants or subject experts cannot vote for decision. They will attend the *IEC Meetings* special invitee as per requirement of the submitted research protocol only.

3.3 Roles and Responsibilities

The *Institutional Ethics Committee (EC)* is set up to ensure that all human research and trial projects are approved and conducted within the specified clinical drug trial site at the Institute and have following *roles and responsibilities*:

- **Appointment of SOP Team:** The **Chairperson** will constitute an *SOP Team* consisting of *Member Secretary* and 5-6 *IEC Members (preferably clinicians, basic medical scientist, lay person/ethicist/social scientist and legal expert)*.
- Projects are sound in scientific design, have statistical validity and are conducted according to the parameters of *ICH-GCP* as well as regulatory requirements.
- Trials do not compromise the safety, rights and well-being of the participant patients who are recruited in the proposed research study.
- Trials are conducted under supervision of *Certified Medical Professionals/Personnels* with the desired experience/expertise.
- Appropriate *Informed Consent* is obtained from the patient and / or legally acceptable representative as per *CDSCO, DCGI and ICMR guidelines*.
- Recruit participant patients who voluntarily sign and authenticate the *informed consent form* and fulfil the illusion and exclusion criteria specified in the protocol and are randomised appropriately.
- Do not expose the study subjects/participants to more than *minimal risk*.
- To review the proposed trial with regards to the following:

  - *The Trial Objectives.*
  - *The Qualification and Competence of the Investigators.*
  - *The sample size calculation.*
  - *The proposed analysis of data.*
  - *The subject/participant patient inclusion and exclusion criteria.*

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- *The exposure of participants to risk.*
- *The extent of medical and laboratory examination proposed.*
- *The procedures proposed to achieve informed consent.*
- *The proposed mechanism to ensure confidentiality.*
- *The details of compensation payable to the volunteers/insurance policy.*

The meeting is organised by the *Member Secretary* in consultation with the **Chairperson.** The *Member Secretary* will maintain minutes of the meeting. Both, the **Chairperson** and *Member Secretary* will sign and validate the minutes of the meeting and subsequently, the *Member Secretary* circulates the minutes to all the members within 2 weeks and issue approval or disapproval letter to the concerned respective *PI*. The **Chairperson** presides over the meeting and *Member Secretary* signs off the approval letter after due perusal from the **Chairperson**. The *Ethics Committee* will review all new research projects and also the ongoing research projects at intervals appropriate to the degree of risk to the study/participant subjects. The *Ethics Committee* will maintain a list of *Research Projects* submitted, approved / disapproved and the outcome of each project. The *EC* will review all new research projects and also ongoing research projects at intervals appropriate to the degree of risk to the study/participant subjects.

The *Ethics Committee* expects from the PI:

- To provide a report of the *clinical drug trial* on an annual basis or more frequently, if deemed by the *Committee.*
- To provide a report of each *Serious Adverse Event (SAE)* with regards to the study.
- To be kept informed of amendments/revisions to any study-related documents as well as patient safety related information.
- To be kept informed of study completion and discontinuation with reasons, thereof.
- To submit justification for approval to restart research studies discontinued earlier.

3.4 Policy Regarding Training for New and Existing Institutional Ethics Committee Members

Each *IEC Member* will maintain in strict confidence and will not disclose or use any information received and discussed during the *IEC Meetings*. If any *IEC Member* happens to be affiliated to some *Pharmaceutical Company*, he/she will not participate in voting process nor will present at the time of voting, if the research project (clinical drug trial), to be conducted at the Institute, of the same *Pharmaceutical Company* has been empanelled in the agenda for discussion and evaluation for the forthcoming scheduled *IEC Meeting*.

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
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MGMC, Jaipur

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3.5 Policy Regarding Monitoring/Prevention of Conflict of Interest and Confidentiality

Each *IEC Member* will maintain in strict confidence and will not disclose or use any information received and discussed during *IEC Meetings*. If any *IEC Member* happens to be affiliated to some *pharmaceutical company*, he/she will not participate in voting process nor will be present at the time of voting during the ongoing scheduled *IEC Meeting*, if the clinical drug trial being sponsored by the same *pharmaceutical company is being discussed and analysed for its merits and demerits.*

3.6. Annual Report Preparation

The *IEC* needs to prepare an annual report to be submitted to **The Principal and Controller,** *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* and needs to include the following:

- A quantitative evaluation of the activities of *Institutional Ethics Committee* in an year.
- The list of research proposal reviewed in an year.
- The status of research proposals

4.0 The Operating Procedure

4.1 Meeting Schedule

The *Ethics Committee* meets once in 6 to 8 weeks and an advance notice of 7 days before the scheduled meeting is sent to all respective *Institutional Ethics Committee (IEC)* [*in online or offline mode*] *Members* along with the agenda. The venue for the offline scheduled *IEC Meeting* is *Ethics Committee Meeting/Conference Hall, Mahatma Gandhi Medical College and Hospital, Jaipur-302022.*

An unscheduled *IEC Meeting* may be convened at the discretion of the **Chairperson** and the *Members of IEC* in view of the following:

- *Final Protocol with all amendments.*
- *Investigator's Brochure (IB) and other safety related information available.*
- *Informed Consent Form (ICF) and Patient Information Sheet.*
- *Insurance Certificate.*

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- *Any other project specific document.*

In conditions of National or Global exigency as in pandemic times, provision for unscheduled and emergency Institutional Ethics Committee (IEC) is laid down through online mechanisms.

4.2 Detailed Procedure for IEC Submission

4.2.1 Receipt of Submitted Research Protocols (Packages)

The *Principal Investigator* can submit research proposals to the *Institutional Ethics Committee (IEC)* for review and approval under any of the following *five (5) categories*:

1. *Initial review Application.*
2. *Resubmission of Protocols with Corrections.*
3. *Protocol Amendment or any other Amendments.*
4. *Continuing Review of Approved Protocols.*
5. *Protocol Completion/Termination.*

4.2.2 Verification of Contents of Submitted Protocols/Packages

The protocols so submitted in the *IEC Secretariat* are verified and checked as to the applicable documents so submitted along with the protocol and it is ensured that all required and necessary forms and materials are contained within the submitted package. The documents so submitted are assessed as per the *checklist for submission for initial review.*

The Verification Checklist includes the following:

- *Application Form for Initial Review or Project Submission Proforma.*
- *Study Protocol.*
- *Other related documents necessary for initial review.*
- *Check completeness of necessary information and signature at all appropriate places in the application form submitted for initial review.*
- *Notify the applicants, if the submitted protocol/package is incomplete.*

State clearly the items missing in the package on *Protocol Submission /Document Receipt Form.*

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The Secretariat Will

- Stamp, sign along with date the receipt form on the covering letter confirming receipt of the documents.
- Make a photocopy of the completed document receipt form and return the original copy to the applicants for their records.
- Count for correct numbers of hard copies (15 copies).
- Store the hard copies and soft copy of the research project. The hard copies will be stored in locked cupboards in the *IEC Office* and soft copy of *IEC submission form/study protocol* accepted by email will be saved on the hard disk (computer's or separate mobile unit).
- Record the date of receipt, number of copies and name of the receiver in documents receipt form.
- Store the received packages, which include original protocol file and copies of the protocol to be distributed for review.

4.3 Detailed Description of Study Project Submission

The study protocol should be accompanied with the following relevant supporting documents for scientific and ethics review inclusive of the following:

1. *Checklist.*
2. *Project Submission Proforma.*
3. *Essential Documents*
   a. *Informed Consent Form*
   b. *Participant Information Sheet*
4. *Decision of Other Ethics Committees (if required/asked for).*

Protocols to include the following:

1. *Title of the Protocol.*
2. *Name and Contact Details of Principal Investigator.*
3. *Name and Contact Details of Sponsor.*
4. *Abstract (Summary/Synopsis).*
5. *Type of Protocol (Screening, Survey, Clinical Drug Trial and Phase).*
6. *Objectives.*

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7. *Anticipated Outcome.*
8. *Inclusion/Exclusion Criteria.*
9. *Withdrawal or Discontinuation of Treatment.*
10. *Schedule and Duration of Treatment.*
11. *Modes of Treatment Studied.*
12. *Methodology.*
13. *Activity Plan / Timeline.*
14. *Efficacy or Evaluation Criteria (Response/Outcome)*
15. *Safety Parameters Criteria (Toxicity Profile).*
16. *Analysis (Methods).*

4.4. Essential Documents Required for Submission

The applicant of the proposal (generally the *Principal Investigator*) is required to submit a copy of his/her application along with 15 copies of the following documents, 21 days before the scheduled *IEC Meeting*:

- *Final copy of Protocol (inclusive of Protocol Amendment) with version number and date.*
- *Final copy of Investigator Brochure (IB) (containing all details of the chemistry, animal studies, toxicology and available clinical data of the trial drug with adequate bibliography) with version number and date.*
- *Copy of Informed Consent Form (ICF) [English] with version number and date.*
- *Copy of Patient Information Sheet [English] with version number and date.*
- *Copy of Informed Consent Form (ICF) [Hindi] with version number and date.*
- *Copy of Patient Information Sheet [Hindi] with version number and date.*
- *Translation and Back Translation Certificate.*
- *Copy of Case Report Form.*
- *Subject Recruitment Material.*
- *DCGI Submission Letter.*
- *Draft of Clinical Trial Agreement*.*
- *Copy of Insurance and Indemnity Letter.*
- *Current signed curriculum vitae of Principal Investigator**.*
- *Number of centres and sample size for each centre.*
- *Material Transfer Agreement (MTA).*
- *CTRI [Clinical Trials Registry of India] Registration ***.*

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- **On format approved by* **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022 between the investigator and the Clinical Research Organisation/Sponsor of the research project / trial and Institution (proforma party).*

- ***Every trial should have Principal Investigator (PI) and a Co – Principal Investigator (Co – PI) who should be a faculty member of the institution. The Principal Investigator, Co – Principal Investigator and Sub – Principal Investigator should only be from the Institution i.e., Mahatma Gandhi Medical College and Hospital, Jaipur-302022 working as faculty of the Institute.*

- ****Undertaking by the Investigator as per the format of New Drugs and Clinical Trials (NDCT) Rules, 2019. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facilities available and related issues with the Investigator. As pre guidelines of NDCT Rules, 2019 regarding restriction of conducting clinical trials per investigator, the number of clinical drug trials a faculty member may undertake at a given time need to be considered, considering the available time and amount of work that a faculty member of the Institute has in terms of academics, patient care, research and administrative responsibilities.*

CTRI Registration, Final Clinical Trial Agreement and DCGI Approval Letter can be submitted later for notification but before start of the study/research project.

**The Ethics Committee is to be notified of any payments proposed to be made to the study participant patients towards reimbursement of incidental expenses.*

4.5. Resubmission of Protocol with Corrections

- For resubmitted protocols, *Principal Investigator* need to submit copies of equivalent to total number of *IEC Members* and one for *IEC record of Amended Protocol* and related documents along with justification for amendment and clearly highlighted / demarcated sections which have undergone amendment.
- The *IEC Secretariat* will verify the completeness and reconfirm that the copy contains the modification highlighted with respect to earlier *Protocol*.
- The *IEC Secretariat* will perform steps as mentioned in initial review application.

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- The protocol related documents which do not require to be changed and are already submitted to the *IEC* during initial review, need to be submitted again.

4.6 Protocol amendment

- The *Principal Investigator* will submit 15 copies of the protocol amendments or any other study related documents to the *IEC Secretariat*.
- The *IEC Secretariat* will verify the completeness as per checklist for the contents of submitted package/protocol.
- The *PI* will highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the *Informed Consent Form (ICF)*.
- The **Member Secretary,** in consultation with the **Chairperson**, will decide whether to:
  - Carry out an expedited review in case of minor administrative amendment.
  - Table for discussion at the full *Institutional Ethics Committee Meeting Review*.

4.7 Annual Continuing Reviews of Approved Protocols

- The *Institutional Ethics Committee (IEC)* will send reminders for annual report to *Individual Principal Investigators (PIs)*.
- The *IEC* will receive a copy of *Annual Study / Continuing Review Report* in the prescribed format for the approved protocol.
- The *IEC Secretariat* will verify the completeness of the *Continuing Review Application Form Progress Report / Request Letter* for extension of approval of the project. The *IEC Secretariat* will sign, validate and date the documents.
- The progress or continuing review report will be tabled in the full *Institutional Ethics Committee (IEC) Meeting*.

4. 8 Protocol Completion

- The *IEC* will send reminders for annual report to *Individual PI*, 15 days prior to the date of completion.
- The *IEC* will receive a copy of Study Completion Report in the prescribed format.
- The *IEC Secretariat* will verify the completeness of the *Study Completion Report Form* filled by the *PI*.
- The study completion report will be tabled in the full *Institutional Ethics Committee (IEC) Meeting*.

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4. 9 Timing of Submission

The *IEC submission package* related to clinic drug trial is submitted at least 21 days before the next scheduled *IEC Meeting*.

4.10 Proceedings of the Meeting and Documentation of Minutes

- The **Member Secretary** designated by the **Chairperson**, records the minutes of the meeting and circulates the same to the members within 2 weeks of the meeting. A study team member may be called to the meeting to present the study or answer specific queries. However, he/she will not participate in the decision making/voting process of that study even if he/she is a regular member of the IEC.
- The decision of the committee is taken by a majority vote after the quorum requirement are fulfilled to recommend / reject / suggest modification for a repeat review or advise appropriate steps. If subject experts are invited to offer their views, they don't take part in the voting process.
- The **Chairman / Member Secretary** convey the decision of the committee to *PI* in writing.

4.11 Approval/Disapproval

The *Institutional Ethics Committee (IEC)* will give its opinion on the research projects (inclusive of *clinical drug trials*) so submitted in one of the following ways:

1. *Approval on a Specific Format*
2. *Disapproval.*
3. *Modification before approval.*
4. *Discontinuation of a previously approved research project.*

In all such cases, the *clinical drug trials* are unambiguously identified by *protocol number* and *title.* All documents reviewed are listed in the response letter, which also states the list of *IEC Members* present and date of *IEC Meeting* during which the said study *(inclusive of clinical drug trials)* was reviewed.
However, if an amendment to a study related document is administrative in nature and not involving study design and/or safety criteria, the same is notified to the *IEC* and acknowledged by the **Chairman/Member Secretary**, accordingly. The **Member Secretary** informs other *IEC Members*

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of the amendment and the decision taken during the subsequent regular scheduled *IEC Meeting*, wherein the decision taken is rectified.

5.1 Informed Consent

The basic requirement in these documents must be as per the *List of Elements of Informed Consent Form (ICF) Elements Checklist*. **The ICF Elements Checklist** [Based on *New Drugs and Clinical Trials (NDCT) Rules, 2019*]. The process of *Informed Consent* need to include full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent with *adequacy, completeness, and comprehension of written and oral information* need to be given to the research participants, and, when appropriate, their Legally Acceptable Representative(s) (LAR). A clear justification for the intention to include research participants who cannot consent with a full account of arrangements made to obtain their consent /authorisation need to be given. Moreover, research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being and will receive response to queries and complaints from research participants or their representatives during the course of a research project.

All Informed Consent Forms (ICFs) and Patient Information Sheets (PISs) must have following essential elements:

S. No.	Checkbox	Items
1	☐	Statement that the study involves research and explanation of the purpose of the Research.
2	☐	Expected duration of the Subject's participation.
3	☐	Description of the procedures to be followed, including all invasive procedures and others.
4	☐	Description of any reasonably foreseeable risks or discomforts to the Subject.
5	☐	Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, Subject should be made aware of this.
6	☐	Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7	☐	Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to Subject's medical records.
8	☐	Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomised trials)

Signatory of SOP approval
Member Secretary, ethics committee

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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 queries, rights of Subjects and in the event of an injury.
11	☐	The anticipated prorated payment, if any, to the Subject for participating in the trial.
12	☐	Subject's responsibilities on participation in the trial.
13	☐	Statement that participation is voluntary, that the subject can withdraw from the study at any time and refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.
14	☐	Any other pertinent information.

5.2 Document Management, Advertisement, Languages

All approved versions of the *ICF* and *PIS* will be used for the administration of the consent.

The *Institutional Ethics Committee (IEC)* is well aware of the importance of advertising for study subject's recruitment in the research project. When such advertising needs to be used, a copy of the advertisement must be submitted and the *IEC* will review the information contained in the advertisement, as well as the mode of its communication, to determine whether the procedure for recruiting subjects affords adequate protection and confidentiality. The *IEC* will ensure that the information in the advertisement is not misleading to the study participant subjects.

This will be applicable for advertisements used within the site at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* or *outside.*

Any written or visual advertisement used for the recruitment of study participant subjects must clearly state that the project is for human subject research and may include:

- Name and contact information of the *Investigator.*
- Purpose of the research
- Inclusion and Exclusion criteria that will be used to recruit subjects into the study
- For any advertisement an indication that the advertisement and the study described therein have been reviewed and approved by the concerned *IEC.*

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5.3 The Standard Operating Procedure (SOP) followed for Select Categories

5.3.1 Vulnerable Subjects

The present times seek no tolerance and sympathy and do not permit any exploitation, whatsoever minor it may be, of its vulnerable members for the sake of obtaining research results. The *Institution Ethics Committee (IEC)* of *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* has established guidelines and regulations to protect the special group of population and the clinical investigators need to be aware of and use these guidelines to explore and seek morally and ethically valid results. The vulnerable population includes that subset of persons' whose ability to protect himself is absent or diminished. The vulnerable and special population has been defined by the IEC of the Institute to include *Vulnerable Population and Special Population*:

S. No.	Vulnerable Population: Capable of Being Physically or Emotionally Hurt	Special Population: of Reduced Autonomy
1	Children (up to 18 years) and Minors inclusive of Ethnic Minorities, Sexual Minorities namely, lesbian/gay/bisexual and transgender (LGBT)	Students
2	Women in special situations inclusive of pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare	Residents
3	Fetuses and Human in Vitro Fertilization	Employees and Staff Members
4	Cognitively Impaired Persons, Unduly influenced either by expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent under duress	Terminally Ill Patients
5	Prisoners, Refugees, Tribals and Marginalized Communities, Migrants, Persons or Population in Conflict Zones, Riot Areas or Disaster Situations	Minorities
6	Orphans, Abandoned individuals, Persons Below Poverty Line,	Subordinates
7	Economically and Socially Disadvantaged	Service Personnel
8	Addicts, terminally ill or in search of new interventions having exhausted all therapies	Pharmaceutical Companies Personnel

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
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A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped, or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

When a trial is to be carried out in the vulnerable populations like the paediatric, geriatric population, pregnant women, etc., the consent of the trial subject and subject's *Legally Acceptable Representative (LAR)* is mandatorily taken and the *IEC* will determine that the proposed protocol and/or other document(s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials. Where required assent of the participant will also be taken and this will be ensured during review and approval of the *ICF*.

The EC will not allow the use of trainees/employees working within the organisation to be used as trial participants' unless students and staff have the same rights as any other potential subject to participate in the research project, irrespective of the degree of risk, provided all of the following conditions exist:

- The research must not bestow upon participating *Institutional Subjects* any competitive academic or occupational advantage over other *Institutional Students or Staff* who does not volunteer, and the researchers must not impose any academic or occupational penal y on those Institutional trainees or staff who does not volunteer.
- The *Institutional Students and Staff* must not be systematically treated differently from *non-Institutional Subjects* as part of the project. Due to the potential for perceived or real coercion to participate, *Institutional Students and Staff* who desire to participate in the research (especially those under the direct supervision of the *PI* or listed research collaborators) must be reviewed by Head of Institution, **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022.*
- Where the protocol indicates that the prior consent of the trial subject or the subject's legally acceptable representative is not possible, the *IEC* will determine that the proposed protocol and/or other document (s) adequately address the relevant ethical concerns meet applicable regulatory requirements for such trials (i.e., in emergency situations). This shall be communicated to the investigator in writing while approving the protocol.

No Research can be Counted as Low Risk if it Involves:

1. Procedures which might cause *mental/emotional stress or distress, moral or cultural offence.*
2. *Personal or sensitive issues.*

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3. *Cross cultural research.*
4. Investigation of *illegal behaviour(s).*
5. Invasion of *privacy.*
6. Collection of information that might be *disadvantageous* to the participant.
7. Use of information already collected that is not in the public arena which might be disadvantageous to the participant.
8. Use of information already collected which was collected under agreement of *Confidentiality.*
9. *Conflict of Interest* e.g., colleague or employer of the research participants, or there is any of her power relationship between the researcher and the research participants.
10. *Audio or visual recording without consent.*
11. *Withholding benefits* from "*control*" groups.

5.3.2 IEC Members Responsibilities in Reviewing Studies on Vulnerable Population

- The *IEC* shall protect rights and welfare of mentally challenged and mentally differently abled individuals who are incapable of giving informed consent or those with behavioral disorders. Proper consent process and documentation of consent should be as per *IEC SOP.*
- Research involving vulnerable populations is not eligible for expedited review or exempt on from review and would be always discussed in full *Institutional Ethics Committee Meeting.*
- This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an *orthodox patriarchal society, or terminally ill cancer patients, pregnant women, human fetuses and neonates, prisoners, children, cognitively impaired person, students, employees, sub-ordinates, AIDS/HIV+ subjects, terminally ill participants geriatric population, vulnerable populations.*
- Representative for the vulnerable group is an individual who understands the issues of that population and has been working with this group. Representative for the vulnerable group may be invited on case-to-case basis.

5.3.3 Review Process

- The *IEC* evaluates whether additional safeguards have been included in the study to protect the rights and welfare of vulnerable participants.
- There needs to be at least one or more individuals who are knowledgeable about or have experience in working with these participants as part of the review process. Member of the *IEC* who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study.

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5.3.4 Requirement for Enrolling Children in Research

- If objective of the research can be met by carrying out research with adults, children should not be involved in the research.
- For clinical evaluation of a new drug the study in children should always be carried out after the *phase III* clinical trials in adults. For studies prior to *phase III* the drug has a therapeutic value in a primary disease of the children.
- There needs to be provision for medical and psychological support for child and parent. A *child's refusal* to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/tested, provided the consent has been obtained from parents/guardian. Before enrolling a child in the study, *parent or legal guardian* of the child needs to sign the *parent consent form* and when the child age is between 7 to 18 years, the *parent or legal guardian* needs to sign *assent form*.
- Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.
- The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- If research involves adults unable to consent, the *Institutional Ethics Committee* must consider additional safeguards to protect their rights and welfare. When conducting non-therapeutic research, consent must be obtained directly from the participant, unless the objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally. However, in such studies the foreseeable risks to the participants must be low, risk to the participant's wellbeing is minimized and low.

The *Paediatric studies at the Institute* include the following as per the guidelines laid down by the *IEC*:

- Clinical Trials
- Relative Bio-Equivalence comparisons of Pediatric formulation with the adult formulation performed in adults, and

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- Definitive pharmacokinetic studies for dose selection across the age ranges of *paediatric patients* in whom the drug is likely to be used. These studies are conducted in the *paediatric patient population* with the disease under study.

- If the new drug is a major therapeutic advance for the *paediatric population*, the proposed trial is started early in the drug development, and this data is submitted with the new drug application.

5.3.5 Requirement for Enrolling Pregnant or Nursing Women in Research

Pregnant or nursing women are in no circumstances the subject of any research in the Institute unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women are not subjects of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

The justification of participation of these women in clinical trials is that they are not deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women are not encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant.

Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made subjects for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

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5.3.6 Requirement for Enrolling Geriatric Population in Research

Geriatric population is included Phase III trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers if,

- The disease intended to be treated is characteristically a disease of ageing; or
- The population to be treated is known to include substantial numbers of geriatric patients; or
- When there is specific reason to expect that conditions common in the elderly are likely to be encountered; or
- When the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric population.

5.3.7 Requirement for Enrolling Other Groups in Research

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.

- Research on genetics should not lead to racial inequalities;
- Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
- 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.
- Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research subjects.

6.0 Review of Research Protocols

Categorisation of Research Protocols

The *Member Secretary*, assisted by *IEC Secretariat*, shall screen the proposals for their completeness and depending on the risk involved in the research proposals categorise them into three types, namely, *Exemption from Review*, *Expedited Review* and *Initial Review*. An investigator cannot categorise his/her protocol in to the above three types.

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6.1 Initial Review

All research presenting with more than minimal risk, research protocols which do not qualify for *exemption* or *expedited review* and projects that involve *Academic Clinical trial, vulnerable population* and *special groups* should be subjected to full review by all the *IEC Members*.

Academic Clinical trial:

(1) No permission for conducting an academic clinical trial shall be required for any drug from the Central Licencing Authority where:

(i) The clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes for a new indication or new route of administration or new dose or new dosage form; and

(ii) The clinical trial referred to in clause (i) has been initiated after prior approval by the Ethics Committee for clinical trial; and

(iii) The observations generated from such clinical trial are not required to be submitted to the Central Licencing Authority; and

(iv) The observations of such clinical trial are not used for promotional purposes.

(2) In the event of a possible overlap between the academic clinical trial and clinical trial or a doubt on the nature of study, the Ethics Committee concerned shall inform the Central Licencing Authority in writing indicating its views within thirty working days from the receipt of application to that effect.

(3) The Central Licencing Authority shall, after receiving the communication from the Ethics Committee. Examine it and issue necessary clarification, in writing, within thirty working days from the date of receipt of such communication:

Provided that where the Central Licencing Authority does not send the required communication to such Ethics Committee within thirty working days from the date of receipt of communication from the said Ethics Committee, it shall be presumed that no permission from the Central Licencing Authority is required.

(4) The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, notified by the Indian Council of Medical Research with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of clinical trial of

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licenced and approved drug or drug formulation for any new indication or new route of administration or new dose or new dosage form for academic research purposes.

6.1.1 Guidelines for Review of Research Protocols of Institutional Ethics Committee

The *Institutional Ethics Committee (IEC) Members* will consider the following criteria when performing the review and /or appraisal of the *research protocol*:

- *Minimise risks to participants;*
- *Risks must be reasonable in relation to anticipated benefits;*
- *Participants are selected equitably;*
- *Informed Consent is adequate, 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;*
- *There are adequate provisions to protect the privacy of participants and to maintain he confidentiality of data, where appropriate; and*
- *Appropriate safeguards are included to protect vulnerable participants.*
- *Ensure that the advertisements do not induce the participants and that Principal Investigator has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.*

6.1.2 Specific Responsibilities of IEC Members for Review of Research Protocol Documents

The *Institutional Ethics Committee (IEC)* assigns responsibilities to the members with the objective to involve every member in decision making process. There should be every attempt to ensure meaningful participation of *Lay Person, Social Scientist and Legal Expert.*

- There may be primary reviewers for the protocol.
- The *Legal Person* of the *IEC* may be the primary reviewer of the contract m evaluating the contract to ensure protection of the research participant, indemnification and arbitration).
- The Lay Person may be the primary reviewer for the informed consent document language, whether it would be understandable to the subjects.
- The *Clinicians* and *Basic Medical Scientists* may be the primary reviewers of scientific aspects of the studies. Other members may also review scientific aspects.

The following mentioned elements shall be considered by respective *IEC Members* while reviewing scientific aspects of the study:

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1. *The appropriateness of study design and methodology to achieve the stated objectives.*
2. *There is adequate conceptual or clinical framework, design, methods and analyses to achieve the aim of the study.*
3. *The statistical methodology (including sample size calculation), is adequately justified to draw sound conclusions.*
4. *There is enough justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.*
5. *The justification for the use of control arms (if controlled arms are involved in the study).*
6. *The criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole.*
7. *There is adequate rationale to conduct the study and to contribute to existing scientific knowledge or clinical practice, or whether study intends to validate, prove or disapprove the validity of existing knowledge.*
8. *For pilot study design, there needs to be potential to lead into a larger and high impact study.*
9. *There is enough rational that study challenge existing clinical practice, contributes in addressing critical barrier to progress in the respective field and the research protocol has been so designed that the results of the study would the potential to be published.*
10. *The regulatory permission for conduct of the study, including but not limited to Health Ministry Screening Committee clearance for international collaborative studies, Memorandum of Understanding and Material Transfer Agreement for national and international collaborative research has been adequately addressed and obtained.*

6.1.3 Evaluation of Qualification of Investigator

1. The *IEC Members* must consider whether the qualifications and training background of the participating investigators relate to the study by reviewing their *Curriculum Vitae*.
2. The *IEC Members* must examine disclosure or declaration of potential *Conflicts of Interest*. 3. The *IEC Members* must confirm whether the facilities and infrastructure at study sites can accommodate the study by reviewing the qualification of study team and by necessary discussion with *Principal Investigator (PI)*.

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6.1.4 Review of Study Participation

6.1.4.1 Informed Consent Review (Overall Review)

The *IEC Members* will examine and look for present of following points while reviewing the *patient information sheet/informed consent form* as per guidelines to review *Informed Consent Document/Patient Information Sheet*:

- *Voluntary, non-coercive recruitment/participation/ withdrawal.*
- *Procedures for obtaining informed consent.*
- *Contents of the Patient Information Sheet namely, title, objective, study design and procedures.*
- *Contents and language of the Informed Consent Document.*
- *Translation and back translation of the Informed Consent Document in the local languages.*
- *Language used should be plain and easy to understand by general public.*
- *Contact persons with address and phone numbers for questions about subject's rights and study or injury.*
- *Privacy and confidentiality.*
- *Risks and discomforts inclusive of physical/ mental / social.*
- *Alternative treatments.*
- *Benefits to participants and to others.*
- *Compensation for participation/for injury that could be either reasonable /unreasonable.*
- *Involvement of Vulnerable Participants.*
- *Provisions for medical/psychosocial support.*
- *Treatment for study related injuries.*
- *Use of biological materials*
- *Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness.*

Examination of Community Involvement and Impact

The *IEC Members* will also consider the following points in the *Protocol, Informed Consent Form/Patient Information Sheet*:

- Community consultation.

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- Involvement of local researchers and institutions in the protocol design, analysis and publication of the results.
- Contribution to development of local capacity for research and treatment.
- Benefit to local communities.
- Availability of study results.

6.1.4.2 Informed Consent Form Review with Respect to Associated Risks and Benefits of the Trial

The *IEC Members* shall review the *Informed Consent Form* with *Lay Person* and *Social Scientist* having an added and specific responsibility to review the *informed consent form*. The *review* shall be done to make sure that subjects are well informed of all the risks and benefits in the clinical trial initially and whenever there is new information available, the *patient information sheet* is amended accordingly and patient is informed of such changes on an on-going basis throughout the trial period. The participant subject should be assured that he/she will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being. New safety information should be promptly communicated to subjects, and should be documented in the source notes and re-consenting should be done in a timely manner (as, and when new information is received).

The *Informed Consent Document* should include the risks and benefits of the trial in a language that the subject can easily understand.

The *Investigator* need to maintain complete narration of the process for obtaining informed consent, including the identification of those who consented as participant patient. Narration should include written and oral information to be given to the research participants, and, when appropriate, their *Legally Acceptable Representative(s) [LAR]* and/or impartial witness (wherever applicable).

There need to be justification whenever *LAR* and Impartial witness are involved in the consent process.
There needs to be provision made for addressing to queries and complaints from research participant or their representatives during the course of the study.
New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner.

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The *IEC Members* may use checklist to verify contents of the Patient Information Sheet:

S. No.	Items
1	Voluntary, non-coercive recruitment/participation/withdrawal
2	Procedures for obtaining *Informed Consent*
3	Contents of the *Patient Information Sheet* namely, *title, objective, study design and procedures*
4	Contents and language of the *Informed Consent Document*
5	Translation and back translation of the *Informed Consent Document* in the local language, Hindi
6	Whenever necessary, provision for *Assent Form*
7	Proper justification whenever vulnerable and special group patients need to be enrolled
8	Language used, plain and easy to understand
9	Contact persons with address and phone numbers for questions about subject's rights
10	Privacy and confidentiality of participant patient is covered
11	Adequate information on risks and discomforts namely *physical/social/mental*
12	Provision for subjects are informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial
13	Explanation of alternative treatments
14	Mention of *benefits* to the participant patient and to others (if there is any)
15	Medical management provision for injuries due to study participation
16	Compensation for participation / for injury
17	Check for provision for signatures with date of participation, person conducting *informed consent discussion*, investigator and witness
18	Participant patient address, nominee details and annual income
19	If audio consenting is required, availability of separate audio-visual consenting (seeking permission from patient for audio video recording) before beginning audio-video consenting process
20	Provision for sharing copy of signed and dated consent form to the patient

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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6.1.4.3 Patient Charter (Rights And Responsibilities)

At the time of consenting, the *Patient Charter* mentioning *rights and responsibilities* should be offered to the patient in a language that the *participant subject* can easily understand. There need to be documentation and evidence that such a charter is offered to the patient. *Patient Charter* should include *Participant Patients' Rights and Responsibilities* as mentioned below.

Rights of Research Participant

- Right to voluntary participate in the *Research Study*.
- Right to information about *Research Study* in an understandable language.
- Right to information regarding *investigational product, duration of study, treatment options available as per standard of care management protocol, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury and/ or death or any compensation provided for participation, in an understandable language.*
- Right to be informed of the *risks, benefits and alternatives of proposed treatments*.
- Right to know about *Institutional Ethics Committee (IEC)* and its responsibilities towards protecting *patient's rights, safety and well-being involved in research project* and to *provide public assurance of that protection*.
- Right to get contact details of **Chairperson** and **Member Secretary** of the *Institutional Ethics Committee (IEC)*.
- Right to informed consent and if necessary, *audio-video consent* before participation in any *Research Study*.
- Right to *privacy* and *confidentiality*.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to be *informed* on *how to voice a complaint* to express concerns, violations of rights and/or grievance.
- Right to receive quality healthcare in a safe, clean environment without discrimination on the basis of race, age, colour, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgemental and non-threatening manner.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records.

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- Right to get 24 hours emergency contact details of research study team.

Responsibilities of Research Participants

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (If available).
- To be complaint with research protocols and procedures
- To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
- To ask question whenever any information (e.g., research study details, diagnosis, treatment) explained by research study team or other healthcare team members, is not understood or any clarification is required.
- To immediately inform research study team, in case of any injury or development of any new medical condition.
- Not to consume any medications without the knowledge of research study team.
- To disclose to research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year, on the first visit itself.
- To provide complete and accurate information about current health status including previous medical history, and all the medications currently ongoing including alternative treatments like *Ayurveda, Homoeopathy, Unani or Herbal Medications*, all records of previous investigations, treatment and of allergic reactions especially sensitivity to any drug.
- To treat hospital staff and study team with courtesy.

6.1.4.4 Waiver for Written Consent

The purpose of this subsection is to describe the type of research studies for which the IEC may approve for waiver for written Consent to the Participants. The applicant should submit waiver of consent request to *Institutional Ethics Committee* along with the desired dossier specifying the reasons for the consent waiver. The *IEC Secretariat* shall check if the concerned documents are filled completely and the required list of documents is enclosed.

While reviewing such application the *IEC* will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.

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The decision whether to grant the waiver can be taken during expedited or full *Institutional Ethics Committee (IEC)* review. The decision regarding approval/disapproval of waiver should be informed to the *Principal Investigator* in writing; however, if waiver request is disapproved, the reasons thereof should be mentioned.

Types of Research Project that may Qualify for Consent Waiver

1. The proposed research presents no more than minimal risk to subjects (regulatory bodies of *CDSCO, DCGI, ICMR guidelines*), i.e., a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests.
2. In case of telephonic interviews, waiver of written informed consent may be approved; however, in such cases verbal consent may be obtained.
3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries and data, documents, records, or specimens that have been collected for non-research (clinical) purposes.
5. In emergency situations when no surrogate consents can be taken (ICMR guidelines), when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the *IEC* can allow waiver of consent for recruiting participant in a research study. However, *informed consent* should be administered whenever participant regains consciousness / capacity to voluntary consent.
6. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective (regulatory bodies of *CDSCO, DCGI, ICMR guidelines*) e.g., conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.

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6.1.5 Institutional Ethics Committee Decision

If the *IEC decision is 'Approved'*, it implies the approval of the study as it is presented with no modifications and the research study can be initiated.

If the *IEC decision is 'Approved with recommendation'* it implies that:

- Requires modifications to items noted in the query letter and project to be re-submitted for review for full *IEC Meeting*.
- Expedited review to be performed by at least 2 *IEC Members* designated by the **Chairperson**.

If the *IEC decision is 'Dis-Approved'*, it implies that the study is *Dis-Approved* in its present form.

Full Institutional Ethics Committee Review of the Documents in Following Conditions

- Even if any one of the *IEC Members* raises an objection for expedited review process, the objections are to be noted in the minutes and conveyed to the *Principal Investigator* as query letter. If any *member/members of the IEC* is/are participating in the research project under discussion, they will opt out from all deliberations on the proposed research project. This will be noted in the minutes of the meeting. The *investigator/sub-investigator* may be called in to provide clarifications on the study protocol that he/she has submitted for review to the *IEC*.
- If the research study is approved, the *IEC* determines the frequency of *Continuing Review* for each *Investigator*.
- The *Member Secretary* will list participating members in the meeting and summarize the guidance, advice and decision concluded by *IEC Members*.

6.1.6 Final Communication of IEC Decision Taken on the Research Project to the Principal Investigator

- The **Member Secretary** or **IEC Coordinator** sends an approval letter to the *Principal Investigator* when the *IEC decision is approved*.

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- The letter contains, at a minimum, a listing of each document approved and a review of other obligations and expectations from the *Investigator* throughout the course of the research project.
- The *IEC Decision Letter* is signed and validated by the *IEC* **Chairperson** or the **Member Secretary** and sent to the *Principal Investigator* within 10 working days.
- If the *IEC* reaches a decision to disapprove the study, the **Member Secretary** or *IEC Coordinator* immediately notifies the *Investigator* in writing about the decision and the reason(s) for not approving the propose research study. A notifying letter to the *Investigator* should state the following: "*If you wish to appeal to this decision, please contact the IEC and submit your appeal in writing addressed to the* ***IEC Chairperson*** *or* ***IEC Member Secretary*** *with justifications as to why the appeal should be granted*".
- If the *IEC* requires modifications to any documents, the **Member Secretary** sends a written request of the specific changes in the form of query letter to the *Investigator* asking him or her to make necessary changes within 90 days of receipt of the *query letter*.
- If the *Principal Investigator* fails to reply within 90 working days, the proposed research study is declared closed for *IEC records*.
- The **Member Secretary** or **IEC Coordinator** will verify the correctness of the wordings and spelling in all letters and process all the above tasks within 10 days after the meeting.
- The **Member Secretary** or *IEC Coordinator* will keep a copy of the *Approved Letter/ Query Letter/Disapproval Letter* in the project file along with all the reviewed documents.
- The letter should specify, if any *regulatory clearance*, *CTRI (Clinical Trials Registry of India) Registration* pending with note that study may be initiated only post required regulatory clearances and *CTRI Registration* (where applicable).
- The *Principal Investigator* is also required to communicate the *IEC* about initiation of patient recruitment.

6.2 Expedited Review

The *Expedited Review* applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

It is the responsibility of the *Institutional Ethics Committee (IEC) Members* to define of which study protocols should be reviewed and approved through expedited channel.

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In case of some specific clinical research projects the *IEC* may consider the need for an expedited review. Such projects need to have a valid rationale for expedited review. The *Members of the IEC* will ensure that such projects are involved with no more than a minimal risk to the study participants. Such reviews will be undertaken by the **Chairperson** or any one of the experienced members designated by the **Chairperson**

The *Expedited Review* can be done in following 2 conditions:

1. If the *IEC Final Decision* in *Full Institutional Ethics Committee (IEC) Meeting* mentions *Expedited Review* of amended documents.
2. If *PI* request any study document to be reviewed through *Expedited Review Process*.

Upon receipt of the *Expedited Review Document Package*, the **Member Secretary** of *IEC Coordinator* will inform the **Chairperson** of the *IEC* verbally and share documents for **Chairperson** review. The **Chairperson** and **Member Secretary** would decide if research study documents can be reviewed through an *expedited review process*. The **Member Secretary** or *IEC Coordinator* will communicate this decision to *PI*.

6.2.1 Receipt of Submitted Documents

The **Member Secretary** or *IEC Coordinator* will receive any of the following documents which can be submitted for *Expedited Review*:

1. Submission of *Letter, Protocol and Protocol related Documents* submitted by the *Investigator* for research projects sent for review for the first time.
2. *Protocol Amendment and related Documents*.
3. *Re-submitted Protocol*.

The **Member Secretary** or *IEC Coordinator* will get the *contents of submitted protocol package (checklist) form*, as per *check items received* and *stamp the receiving date on the documents*.

6.2.2 Determination/ Categorisation of Research Protocols for Expedited Review

The **IEC Member Secretary** and **Chairperson** will determine whether a study is qualified for expedited review according to the following criteria:

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1. Proposals submitted for *initial review* satisfying any of the following criteria:

   - Interviewing of a non-confidential nature, not likely to harm the status or interests of the individual.
   - Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of *electroencephalogram (EEG)*or *electrocardiogram (ECG) electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance*, etc. However, procedures involving the use of *x-rays or microwaves are not recommended* for *expedited review process*.
   - The research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

2. Modifications / amendment of protocol and related documents (approved earlier) if the change involves any of the following:

   - Administrative revisions.
   - Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
   - Non-significant risk research activity.
   - The research activity includes only minor changes from previously approved protocol.

The *research protocol* reviewed earlier and the *IEC decision* was to '*Approve after the Principal Investigator incorporates the suggestions to be subjected for Expedited Review*'.

6.2.3 Expedited Review Process

- The **Chairperson** nominates 2 or more *IEC Members* to review the revised protocol, who then report the decision to the scheduled full *IEC Meeting*. An *Expedited Review* is a speedy one for minor changes to the approved protocol and for research proposal with minimal risk in nature.
- The **Member Secretary** or *IEC Coordinator* sends the revised protocol to the selected members who will perform the *Expedited Review* on the complete proposal.

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- If consensus cannot be reached, the members conducting the *expedited meeting* will refer the research proposal back to the *IEC* for a full *IEC Meeting review*. The IEC *decision* will be recorded on the *IEC Decision Form*.
- The *Expedited Review* should not take longer than 14 Working days post submission of amended documents from *Principal Investigator*.
- The Member Secretary will inform the I*EC Members* of the proposals approved by *Expedited Review* at its regular scheduled meetings and source documentation of the items in the meeting agenda / notes.

6.2.4 Communication of Institutional Ethics Committee (IEC) with Principal Investigator (PI)

- The **Member Secretary** or *IEC Coordinator* will forward the *Research Project Protocol IEC Decision* letter to the *Principal Investigator.*
- If it is approved, disapproved or requires resubmission after certain modifications, this is informed to the *Principal Investigator* in writing within 5 working days.

6.3 Resubmitted Research Study Protocols Review

This is applies to study protocols that have been reviewed earlier with recommendations from the *IEC* for some corrections in the initial review process.

The *IEC Member Secretary* or *IEC Coordinator* will ensure the completeness of the resubmitted documents and will inform the **Chairperson** that a protocol previously approved with conditions for revision has been resubmitted to the *IEC* for reconsideration.

A re-submitted protocol may be reviewed and approved by either the **Chairperson** or some *IEC Members* designated by the **Chairperson**, or full *IEC* as per *IEC decision* determined by the *IEC*, at the time of the initial review of the project during the full scheduled *IEC Meeting*.

Resubmitted Protocol should be submitted with following documents:

- Reply to the *query letter* addressing the corrections within 90 days of receipt of the letter.
- Revised version of protocol and related documents such as the *informed consent document, data collection or case report form, diary sheets, etc.* are included as a part of the package with the changes made to the documents are underlined or highlighted.

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6.4 Ongoing review

The *Institutional Ethics Committee (IEC)* will conduct ongoing review of clinical research projects at regular intervals, *but not less than once in a year (it can be early depending on the risk status of the trial or if it involves vulnerable population).*

Ongoing review of trial shall be done for continuation, risk evaluation and adverse event monitoring.
Ongoing review is review of the trial status and analysis of risk to subjects in an ongoing trial previously approved by the *IEC*. The *Principal Investigator (PI)* is made aware of the periodicity to submit the documents for review. It can be communicated through final *IEC decision letter to PI.*

The *IEC* has the authority to revert the decision of a proposal initially approved based on the periodic assessment of risk to the trial participating subject.

6.5 Amendment Review

In case of any *amendments* to the *Research Study Protocol (already approved by the full scheduled IEC Meeting) or any other study documents,* the *IEC* must be notified. The *Amendment Review IEC Fees is Rs 25,000/- (R.s Twenty Five Thousand Only)* per amendment.

The *Amendments* made to the duly approved *IEC Research Clinical Drug Trial Protocol* will not be implemented until reviewed by the *IEC.*

The **Member Secretary** or *IEC Coordinator* will confirm the request for *Amendment Memorandum of the Protocol/Protocol related documents from the Principal Investigator* on an existing and previously approved *Protocol/Protocol related documents*. The memorandum should:

- State/describe the amendment.
- Provide the reason for the amendment.
- State any untoward effects with original protocol.
- State expected untoward effects because of the amendment.

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The changes or modifications should be underlined or highlighted or summary of changes to be submitted.

The *Amendment Review process* would be similar to *Initial Review*.

6.5.1 Technical

The amendment to the protocol will be considered technical if:

Any change in drug dosage or duration of exposure to the study medication beyond that in the current protocol.

- Any significant increase in the number of subjects.
- Any significant change in the design of the protocol.
- Any addition of a new test or procedure.
- Any other change which may affect the health of the study subject.

In case of such *amendments*, the *Investigator* must submit the following *Documents* to the *Institutional Ethics Committee (IEC)*:

- 15 copies of *amended protocol* with mention of *Amended Protocol Number and Date.*
- Table of *Amendments* with rationale for the *amendment*.

The *Institutional Ethics Committee (IEC)* will review the amended protocol and the changes will be implemented only after the favourable approval. The sponsor must obtain a favourable approval from the respective *Regulatory authorities* and submit a copy of the same to the *IEC*.

6.5.2 Administrative

In case of change in the *Investigator* for an approved protocol, the *Sponsor* needs to inform the *IEC* of the change along with the updated *Curriculum Vitae (CV)* of the *new Investigator*.
In case of any administrative changes to an already approved protocol like address change, the *Sponsor* needs to notify to the *IEC* of the changes and the reason for the change. The **Member Secretary**, will acknowledge the receipt of such amended version and the study can continue.

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6.5.3 Communication of the Decision to the Principal Investigator

If the *IEC* approves the protocol amendment, the **Member Secretary** or *IEC Coordinator* communicates this decision to the *Principal Investigator*. The **Member Secretary** or *EC Coordinator* sends a duly validated signed and dated *Amendment Approval letter* to the *Principal Investigator (PI)* for their records no later than 15 working days of the meeting of the *IEC*.

If the *IEC* does not approve the protocol amendment, the **Member Secretary** or *IEC Coordinator* immediately notifies the *Principal Investigator* in writing of the decision and the reason for not approving the amendment.

If the *IEC* requires modifications to any of the documents, or the protocol amendment, the **Member Secretary** sends a written request about the specific changes to the *Principal Investigator* asking him or her to make the necessary changes and resubmit the document to the *IEC*.

Store Documents

The **Member Secretary** or *IEC Coordinator* will keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the *IEC* as the official records of the amendment review process.

The **Member Secretary** or *IEC Coordinator* will place the original completed documents, the amended version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

6.6. Safety Review

The *IEC* ensures that all clinical trials being conducted at the site report all serious adverse events with their follow up to the EC as per the timelines specified in the protocol or applicable guidelines.

All serious adverse events that occur at the site are reported to the EC within 24 hereof the occurrence and discussed during *IEC Meetings*.

In case of any adverse events, the Investigator must send the same in the Interim Report to the *IEC*.

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In multi-centre studies, investigators are required to report serious adverse experiences that occur in subjects enrolled at other participating sites, both in India and abroad within 14 working days from the date they are received at the site.

All safety reports will be addressed to the **Chairperson/Member Secretary** and submitted to he **Chairperson/ Member Secretary** who will acknowledge the receipt.

All safety reports received by the *IEC* will be reviewed by the **Member Secretary** and he/she will put up the same for review by the *IEC Members*. If an adverse event poses serious and unnecessary risk to study subject safety, the **Chairperson** or the *Members* as a whole may immediately suspend the study.

In the event of a death of a study subject, the *Investigator* must submit the report immediately but not more than 24hrs along with the post mortem report, if available.

The *Institutional Ethics Committee* will review all the *Serious Adverse Events* and decides for the compensation /Medical Management in case of death or injury as per the guidelines laid down by the respective *regulatory body of CDSCO, DCGI, New Delhi.*

6.6.1 On site Serious Adverse Event (SAE) Reports Review

- If patients enrolled at site experiences *Serious Adverse Event (SAE)*, the *Principal Investigator (PI)* needs to submit the *SAE* report within 24 hours of their occurrence and with due analysis within 14 calendar days and necessary follow up reports. The *Sponsor* needs to submit the *SAE* report with due analysis within 14 calendar days.
- The *PI* is required to share information on compensation is paid to the subject as per *Informed Consent Document* contract and applicable rules and regulations. The amount paid should be approved (to be verified only) by the *Institutional Ethics Committee (IEC).*
- In case of pregnancy as *SAE*, the *PI* needs to send follow-up reports of the child in utero and post-delivery of the baby till 1 year.
- The *IEC Secretariat* will receive the *SAE* report or the unexpected event report occurring at the trial site approved by the *IEC* for a given project. The *IEC Secretariat* will review report to make sure they are complete, signed and dated by the *Principal Investigator (PI)* or qualified study team member (in absence of *PI*) and is received at the *IEC Office* within 24 hours of occurrence of the *SAE.*

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- The *IEC Secretariat* will verify that the report for its completeness and also shall verify if stipulated timelines are followed as per relevant regulations.
- The *IEC Members* reviewing SAE documents shall evaluate if adequate medical care is provided for *Serious Adverse Events (SAE)* as per applicable rules and regulations.
- The *SAE* reports will be reviewed by *IEC* so as to determine relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per relevant guidelines with effect from time to time.
- If appropriate to the discussions, the members may call for a consensus on whether to:
- Request an amendment to the protocol or the consent form,
- Request further information,
- Terminate the study.
- The *Decision* should be noted in Minutes of Meeting and also communicated to the *Principal Investigator*.

6.6.2 Process for Root Cause Analysis for On-Site Serious Adverse Event (SAE)

The *IEC* would be responsible for *Root Cause Analysis (RCA)* of *Serious Adverse Event (SAE)* occurring at site. The *RCA* process would be able to trace root causes of *SAE* and thereby enabling changes to be made to protocol or processes to prevent the incident from reoccurring. An *RCA* needs to assess the details, the causes and the reasons thereof for the *SAE*.
The *Root Cause Analysis (RCA)* will also help to determine of whether there is a reasonable possibility that the product is causally related to the serious adverse event. The *Root Cause Analysis (RCA)* shall also include evaluation of temporal relationships, de-challenge/re-challenge information (f available), association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, and biologic plausibility.

The *IEC* shall be guided by following mentioned assessment criteria for *Root Cause Analysis (RCA)* of *Serious Adverse Events (SAEs)*.

1. Relation of SAE to Study Drug on Satisfaction of Following Criteria

- Event or laboratory test abnormality, with plausible time relationship to drug intake.
- Cannot be explained by diverse or other drugs.
- Response to withdrawal plausible (pharmacologically, pathologically).
- Event definitive a recognised pharmacological phenomenon.

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Institutional Ethics Committee
MGMC, Jaipur

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- Re-challenge satisfactory (if such data is available).

2. Criteria of Causality Assessment/Relatedness of SAE Relating to Study Drug

- Event or laboratory test abnormality, with reasonable time relationship to drug intake.
- Unlikely to be attributed to disease or other drugs.
- Response to withdrawal clinically reasonable.
- Re-challenge not required.

3. Possible Relation of SAE to Study Drug Satisfying Following Criteria

- Event or laboratory test abnormality, with reasonable time relationship to drug intake.
- Could also be explained by disease or other drugs.
- Information on drug withdrawal may be lacking or unclear.

4. SAE is Unlikely Related to Study Drug Satisfying Following Criteria

- Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible).
- Disease or other drugs provide plausible explanations.

SAE is un-assessable if more data for proper assessment needed, or if additional is under examination or if information is insufficient or contradictory or if data cannot be supplemented or verified.

6.6.3 Off Site SAEs Review

- The *Principal Investigator (PI)* or *Designate Study Team* should report *Off Site SAEs* to *IEC*.
- If *PI* notices any particular trend in *SAEs*, the same needs to be intimated to *IEC*.

Off-Site SAEs (PSUR)

- The *Member Secretary* shall file the *PSUR/Line listings* submitted by *PI* as a detailed review of the same is out of the scope of *IEC*.
- It is the *PI's* responsibility to review the listings in detail and report if a trend is observed and communicate the same to *Member Secretary, IEC*.

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- The offsite *SAEs* are received in the table format as mentioned below and one copy is acknowledged and returned to *PI.*
- If any queries are raised by any *IEC Member*, the **Member Secretary** shall write to *PI* (by email or letters, as applicable) or else the *Offsite SAEs* are filed in the respective project files.

Action Taken by IEC Depending on Trend Observed by PI

- Direct the PI to inform participants already enrolled in the study about the SAE and if required re-consent these patients.
- Request additional details or recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- Suspend enrolment of new research participants.
- Suspend the study till amendments requested for by the *IEC* are accepted.
- Suspend the study till additional information is obtained.
- Suspend the study till review is completed.
- Terminate the study.
- Any other appropriate action.

6.6.4 IEC Decision Communication

- The *IEC Secretariat* shall communicate the decision to the central regulatory *Licensing Authority of CDSCO, DCGI, New Delhi* within 30 calendar days of the occurrence of the SAE.
- The *IEC Secretariat* shall also communicate final decision to *Principal Investigator (PI)* within a period of 5 days from the date of the SAE Discussion.
- If any query is put forward, the *PI* needs to give a reply within 3 working days.
- If any recommendations from full *Institutional Ethics Committee Discussion* are observed, the same shall be communicated to *CDSCO, DCGI* and *PI* as well.

6.7 Site Monitoring Visit, Audit Visit, Third party Inspections

6.7.1 Initiation of Site Monitoring

The *Institutional Ethics Committee (IEC)* has constituted a sub-committee, **Data Safety Monitoring Committee (DSMC)** that would assess the site duly approved site by *CDSCO, DCGI* (also in situations when *DCGI site approval is awaited)* in *terms of record keeping, site screening log and enrolment log inclusive, of case record form and informed consent, infrastructure,*

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manpower, personnel and emergency measures available commensurate with the work and patient load on a regular basis, the report of which would be tabled in scheduled full *IEC Meetings* for assessment and approval, accordingly. A high number of protocol violations, large number of studies carried out by the *PI* at the study sites, remarkable *SAE* reports, high recruitment rate, non-compliance or suspicious conduct and any other cause would also be assessed by *DSMC* as per mandate of *IEC*.

Clinical trials sponsored by external funding sources and industry are continually audited for compliance and monitored for progress by the external monitors. However, *IEC* shall monitor all studies irrespective of study monitoring by external monitors.

6.7.2 Before the Visit

· For cause/routine monitoring of research projects, the *IEC* **Chairperson** or **Member Secretary** will designate an *IEC Member* to perform the task of monitoring.
· The **Member Secretary** or *IEC Secretariat* will inform the *Principal Investigator (PI)* in writing about the date/time of monitoring visit and request for confirmation letter from the *PI* to be available for the monitoring visit.
· The *IEC Member* will review the *IEC research project files of the duly approved study and site profile* and make appropriate notes.
· The *IEC Member* may refer *IEC project files* for comparison with the site files.

6.7.3. The Responsibility of IEC Members During Site Monitoring Visit

1. Review the *informed consent document* to make sure that the site is using most recent version, also to ensure that that the subjects are well informed of all the risks and benefits in the *clinical drug trial* initially and on an on-going basis throughout the trial period. New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner. There should be evidence that queries and concerns of subjects are addressed.
2. Review randomly the participant subject files to ensure that subjects are signing the correct *IEC* approved *informed consent form*.
3. Observe the *informed consent process*, if possible.
4. Observe laboratory and other facilities necessary for the study at the site, if possible.
5. Review the project files for the study to ensure that documentation is filled appropriately.

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6. Collect views of the study participants, if possible.
7. Review *SAE documents* to ensure that compensation is paid to the participant subject as per *informed consent document contract* and other applicable rules and regulations. The amount paid should be approved (to be verified only) by the *Institutional Ethics Committee (IEC).*
8. Evaluate if adequate medical care is provided for *Serious Adverse Events (SAEs)* as per applicable rules and regulations.
9. Fill the *Site Monitoring Visit Report Form* and write the comments.
10. Evaluate *protocol violations* or *deviations* to make sure to track for injury to the subject due to noncompliance of protocol.
11. *IEC Members* conducting site monitoring visit may contact the participant patient randomly to understand if there are any patient grievance.
12. Ensure that the advertisements do not include the participant subjects and that *PI* has a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

6.7.4 After the Visit

The *IEC Member* will complete the report within 15 working days and present the findings of the monitoring visit and during the forthcoming scheduled full *IEC Meeting*. If the *IEC Member*, who visited the site, is unable to attend the *IEC Meeting,* then he/she can courier the Monitoring Visit Report with relevant comments and the *IEC* **Member Secretary** can present the same.
The **Member Secretary** or *IEC Coordinator* will place the report in the correct site files.
The full *IEC* recommendations to change the study/ premature termination/ continuation of the project would be communicated to the *PI* in writing within 15 working days of the meeting. The *IEC* can suggest any areas that need to be improved based on the findings of their monitoring reports.

The *IEC* can conduct an Audit visit at the site in case of any non-compliance reported to the *EC.* These reports may follow information to the *IEC* from the study subjects, public, sponsors, progress reports and safety reports. The *IEC* will review such allegations of non-compliance and assess whether such allegations/alleged practices would cause injury or other unanticipated harm or risk to subjects or others involved in the trial. In such cases of alleged non-compliance, the *IEC* may suspend the trial following a review by the full committee. Such decisions will be intimated to the Investigator and the Sponsor in writing. Any complaint of injustice by the study subject will be looked into seriously.

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The EC is open for inspections by respective *Regulatory Bodies*. The documents related to the clinical trial projects reviewed by the *IEC* can be inspected by the regulatory agencies.

6.8 Interim Reports

The *Principal Investigator (PI)* must submit to the *IEC* a progress report on the clinical trial yearly from the date of first approval with respect to specific study:

- Number of subjects screened, enrolled, completed and withdrawn.
- Current status of enrolment.
- Any safety issue.

6.9 Study Completion (Scheduled, Premature, Suspension)

The *Investigator* must submit a final report to the *IEC* on the successful completion of the clinical drug trial at the site.

6.9.1 Authority of Institutional Ethics Committee (IEC) to Suspend, Prematurely Terminate Approved Clinical Drug Trial

- It is not being conducted in accordance with the *IEC's* requirements.
- It has been associated with *More than Anticipated, Unexpected, Serious Adverse Event.*
- It exposes the study participant subjects to more risks.

Any such suspension or premature termination of approval will be informed to the *Investigator* and the *Sponsor* in writing and will include the reasons for the action. The suspension of a clinical drug trial research project may be temporary till the corrective actions are taken and intimated to the *IEC*. The *IEC* will review the corrective actions and will determine the necessary and appropriate action. In case of premature termination of a clinical drug trial research project, further enrolment at the site will be stopped, but the enrolee subjects will undergo the follow up activities required to protect the subjects form any safety issues.

6.9.2 Institutional Ethics Committee Decision

- The **Member Secretary** will notify the **Chairperson** regarding the recommendation for premature termination of study protocol and send a copy of the termination package to the Chairperson within one working day upon receipt.

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- The **Chairperson** reviews the results, reasons and accrual data and calls for an emergency meeting/regular *scheduled full Institutional Ethics Committee Full Meeting* to discuss about the recommendation.

- The **Member Secretary** or *IEC Coordinator* will do the necessary arrangement as per decision of **Chairperson**.

- The **Member Secretary** in the meeting will inform of the premature termination of the project and the *IEC Members* will review the *Premature Termination Report.*

- The **Chairperson** / *Member Secretary* signs, validates and dates the study termination report in acknowledgment and approval of the termination.

- If the *Premature Termination Report* is unclear/more information is required from the *Principal Investigator* the **Member Secretary** or *IEC Coordinator* is instructed to send a query letter to the *Principal Investigator.*

Storage of Protocol Documents

- The **Member Secretary** or *IEC Coordinator* will keep the original version of the *Premature Termination Report* in the Protocol file and send the file to archive.
- The protocol documents will be archived as per guidelines specified in *IEC SOP.*
- If query letter is sent to *Principal Investigator*, on receipt of the reply letter, it is reviewed in the *forthcoming scheduled Institutional Ethics Committee Meeting.*

6.10 Deviation/Non-Compliance/Violation

The *Institutional Ethics Committee (IEC)* has formulated instructions for stringent action and maintenance of records that identifies investigators/trial sites that fail to:

- Follow the procedures written in the approved protocol.
- Comply with National and International guidelines or procedures mandated by the *Institution Ethics Committee (IEC)* for conduct of *research on human participant subjects.*
- Respond to the *IEC* requested regarding statutory, ethical, scientific or administrative matter.

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6.10.1 Detection of Protocol Deviation/Non-Compliance/Violation

The following is the schemata for detection of *protocol deviation/non-compliance/violation* adopted by the *Institutional Ethics Committee (IEC)*:

1. The *IEC Members* performing monitoring of the project at the trial site can detect *protocol deviation/non-compliance/violation*.
2. The Member Secretary or *IEC Coordinator* can detect *protocol deviation/non-compliance/ violation* for failure to comply with statutory requirements/failure to respond to requests from *IEC* within reasonable time limit/failure to respond to communication made by *IEC*.
3. The *Principal Investigator* himself may forward *protocol deviation/non-compliance/ violation* reports to inform the *IEC*.

Noting Protocol Deviation/Non-Compliance/Violation

- The *IEC Members* who have performed monitoring of a particular trial site and detect *protocol deviation/non-compliance/violation* will inform the **Member Secretary** or *IEC Coordinator*. The **Member Secretary** or *IEC Coordinator* would keep record of *protocol deviation/non-compliance/violation* from the *project files/protocol deviation/non-compliance/violation letters* forwarded by the *Principal Investigator* or forwarded by *IEC Members*.

- Whenever *protocol deviation/non-compliance/violation* have been observed the **Member Secretary** will ensure that the issues as well as the details of non-compliance involving *Research Investigators* are included in the agenda of the *Full Institutional Ethics Commitee (IEC) Meeting*.

- The *IEC* should evaluate protocol violations to make sure to track for injury to the subject due to noncompliance of protocol.

6.10.2 Institutional Ethics Committee (IEC) Decision

- If the *Protocol Deviation/Non-Compliance/Violation* are detected by *IEC Member* during monitoring visit he/she will forward these findings to **Member Secretary**. The **Member Secretary** will discuss the findings with the **Chairperson** and decision will be taken whether

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to discuss in regular upcoming meeting or an emergency meeting needs to be called in for discussion of the said findings.

- The *IEC* will review and will take any one of the following action in 'consensuses'.
- Ask PI for required training to avoid deviation.
- Suspend the study till information available.
- Terminate approval of the current study.
- Refuse subsequent applications from an investigator cited for non-compliance.
- The *IEC* will take appropriate action depending upon the nature and severity of *deviation/non-compliance/violation.*
- This action is recorded by **Member Secretary** or *IEC Coordinator.*

6.10.3 Notification to the Principal Investigator

- The **Member Secretary** or *IEC Coordinator* will send a recommendation letter signed by he *Institutional Ethics Committee (IEC)* **Chairperson** or **Member Secretary** to the *Principal Investigator (PI)* if the decision was 'request the *Principal Investigator* not to perform such *deviations/non-compliances/violations* in future'.

- The **Member Secretary** or *IEC Coordinator* will send a project suspension/termination letter signed by *IEC* **Chairperson** or **Member Secretary** to the *PI* if the decision was '*suspend the study till information available/terminate approval of the current study*'.

- If the decision was '*refusal of subsequent project applications*' from the *PI*, this notification letter signed by *IEC* **Chairperson** or **Member Secretary** will be sent to the *PI.*

- The copy of project *suspension/ project termination/ Principal Investigator notification of refusal to accept application from him/her due to Non-compliance* will also be sent to the *CDSCO, DCGI and /or Sponsor.*

- One copy of all the letters is kept in the project file by the **Member Secretary** or *IEC Coordinator.*

- The **Member Secretary** or *IEC Coordinator* will maintain a file that identities investigators who are found to be non-compliant at monitoring visits or with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the *IEC* request for information/action.

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7.0 Emergency Meeting

The provision for *Emergency Meeting of Institutional Ethics Committee (IEC)* has been laid down to address *emergent urgent matters relating to safety/life-threatening/pandemics/epidemics/ endemics issues* that mandate an exigent action through *full IEC review.*

Criteria for Emergency Meeting

The Chairperson will decide to call an emergency meeting based on the following criteria:

- Urgent issues (if delayed will affect or have impact on patient safety, to the public benefit, national economies, international issues with potential impact on *survival of humankind*, etc.).
- Occurrence of unexpected *Serious Adverse Events (SAEs).*
- A matter of life and death for the patients continuing in the duly *IEC approved clinical drug trial.*
- Other appropriate reasons.

The *IEC Secretariat* will contact *IEC Members* and inform them about the meeting lay stress on adhering to the quorum requirement of the regulatory bodies namely,

- *At least One basic Medical Scientist Member.*
- *At least One Clinician Member.*
- *At least One Legal Expert Member.*
- *At least One Social Worker/Ethicist/NGO Representative/Theologian/Philosopher Member.*
- *At least One Lay Person Member.*

The following guidelines need to be adhered by **Member Secretary** or *IEC Secretariat*:

- Collection and verification all forms/documents for completeness to keep all these papers in the *IEC Meeting.*
- Preparation of Meeting agenda mentioning the *mode (offline and/or online)* and *location/ venue, date and timing* of proposed *IEC Meeting.*

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The scheduled *Institutional Ethics Committee (IEC) Members Meeting* would be held at a time interval of 6-8 weeks and the agenda and documents related to the research projects, outlined in agenda, need to be circulated with respective *IEC Members* 10 working days in advance of scheduled forthcoming *IEC Meeting*.

8.0 Agenda, Minutes and Conduct of Meeting

8.1 Standard Operating Procedure (SOP) Inducts Preparation, Review, Approval and Distribution of Meeting Agenda, Minutes and Action, Invitation Letters of Institutional Ethics Committee (IEC) Meetings

The **Chairperson** or **Member Secretary** should review and approve the agenda and minutes of meeting.

The *IEC Secretariat* will prepare agenda to include the following:

1. *All research projects submitted for initial review.*
2. *All submitted protocols wherein IEC decision needs full IEC Meeting.*
3. *Review of Amended Protocols/Protocol Related Documents wherein decision of full IEC Meeting review is needed.*
4. *Continuing review of ongoing study protocols.*
5. *Review of study completion reports.*
6. *Review of premature study termination.*
7. *Review of Site Monitoring Visit Reports.*
8. *SAE Reports/CIOMS forms/Safety Letters.*
9. *Protocol Deviation/Protocol Violation/Non-Compliance.*

The **Member Secretary** or *IEC Coordinator* will prepare the meeting agenda that mentions the date, time and location of meeting and collect and verify all forms/documents for completeness to keep all relevant papers in the *IEC Meeting*. The full *IEC Meeting* is held every 6-8 weeks either in an *offline or online mode* as per mandate of prevailing conditions (inclusive of *pandemic guidelines).*

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8.2 Meeting Schedule and Its Conduct

The *Institutional Ethics Committee (IEC)* will hold regular scheduled meetings at time interval of 6-8 weeks and in the situation when no research projects have been received by the *IEC Office*, the *IEC Meeting* may be held less frequently, but no less than every twelve (12) weeks.

The iIEC Meeting will be held as per scheduled program observing strictly the mandate of the *quorum* as laid down in *New Drugs and Clinical Trials Rules (NDCT), 2019* that needs to essentially include the presence of the following *IEC Members*:

1. *At least One basic Medical Scientist Member.*
2. *At least One Clinician Member.*
3. *At least One Legal Expert Member.*
4. *At least One Social Worker/Ethicist/NGO Representative/Theologian/Philosopher Member.*
5. *At least One Lay Person Member.*

- The **Member Secretary** will obtain signatures on the *Confidentiality/Conflict of Interest Agreement* from the newly appointed *IEC Members/Guests/Observers/Independent Consultants* prior to start of the *IEC Meeting.*
- The **Member Secretary** will also obtain signatures of all *IEC Members* on the attendance sheet.
- The **Chairperson** will initiate the meeting once the quorum has been met. The **Chairperson** will reassess the quorum when any *IEC Member* withdraws from decision making and this will be recorded in the minutes.
- The **Member Secretary** then reports on the minutes of previous meeting and presents the agenda for discussion.

- The meeting proceeds in the order organised in the agenda; however, the **Chairperson** may allow some switching depending on the situation.

- The *Investigators* are allowed to present their projects in brief (a powerpoint presentation with number of slides being limited to 8-10) defining with clarity the *aims and objectives, methodology (inclusive of inclusion and exclusion criteria), mechanism of action of the investigational drug along with risk-benefit and safety profile* and *relevance* of the use of the proposed *investigational drug* and to clarify any queries related to the research project the the *IEC Members* may have.

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- During the approval process, the **Member Secretary** gives a briefing about the study by reading the comments and evaluation of the reviewers.

- The *IEC Members* give their comments right after the presentation and evaluation and discussion on the proposed research study takes place from all angles of science, ethics, societal and legal issues.

- The **Member Secretary** records the discussion and decisions taken during the meeting.

8.3 Minutes of Meeting

The **Member Secretary** will compose the summary of each meeting discussion and decision in concise and easy-to-read style in minutes.

The **Member Secretary** will make sure to cover all contents in each particular category inclusive of the following:

- Name of person preparing the minutes.
- Location where the meeting was held.
- Meeting date/duration of the meeting.
- Names of attending *Institutional Ethics Committee (IEC) Members.*
- Name of individual serving as **Chairperson** of the meeting.
- Determination of a duly constituted quorum by the **Chairperson** to proceed with the meeting. The **Chairperson** will assess the quorum when any member withdraws from the decision making and this will recorded in the minutes.
- The details of risk-benefit assessment for protocols reviewed.

The **Member Secretary** will check the correctness and completeness of the minutes and prepare it within 10 working days of the meeting held. The **Member Secretary** or *IEC Secretariat* shall email *minutes of meeting* to all *IEC Members* for review and comment. The *IEC Members* shall reply within 5 working days with comments, suggestions or modifications, if required. If there is no reply within 5 working days, then the *minutes of meeting* shall be considered accepted.

The **Member Secretary** or *IEC Coordinator* will send minutes of meeting for **Chairperson** or **Member Secretary's** signature.
The **Member Secretary** or *IEC Coordinator* will place the minutes in the minutes file.

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9.0 Fees

The Institutional Ethics Committee (IEC) processing fees for review of Clinical trial/ Drug trial shall be Rs. 60,000 (for trials of total budget less than 10 lakhs) and Rs. 75,000 for budgets of more than Rs. 10 lakhs plus GST as applicable (presently 18%). This fee shall be deposited before submission of the trial for processing by the Ethics Committee to the Account Officer, MGMC&H by cheque/DD drawn in favour of "*Mahatma Gandhi University of Medical Sciences and Technology*," payable at Jaipur. Alternatively, the amount can be deposited through NEFT/RTGS in the bank account, detail given hereunder. After the drug trial is approved following shall be the schedule of charges:

1. Rs. 10,000 (Rs. Ten Thousand Qnly) for archival of official documents papers submitted to Ethics Committee.
2. Amendment fees Rs. 25,000 (Rs. Twenty Five Thousand Only) per amendment.
3. Annual review fees Rs. 30,000 (Rs. Thirty Thousand Only) for budget of less than Rs.10 lakhs and Rs. 45,000 (Rs. Forty Five Thousand Only) for budgets of more than Rs.10 lakhs.
4. The annual review charges shall become due and be deposited on completion of 1 year from the date of approval by the Ethics Committee.
5. GST as applicable will be extra on all Ethics Committee fees.

Bank detail for deposit of cheque/DD/NEFT/RTGS:-
Account No.:83911010000026
Account type: Bank Name: Canara Bank
Branch: M G University, Sitapura, Jaipur Rajasthan 302022
IFSC Code: CNRB0018391
MICR: 302015035

The rest of the funding for the clinical drug trial shall be in name of Principal Investigator. For investigator-initiated trials, non-drug trials, trials by UG/ PG/Ph.D. towards thesis/original research, and for Research sanctioned by State DST, Central DST, ICMR, CSIR & Self Initiated Academic Trials , **no Ethics Committee fees shall be charged.**

10.0 Maintenance of Active Study File

The circulation and maintenance of active research study files and other related documents approved by the *Institutional Ethics Committee (IEC).*

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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10.1 Record Keeping

The *IEC* shall follow regulatory guidelines of respective regulators and all records shall be maintained in the *IEC Office* located at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022*. It shall be restricted access to authorised personnel with adequate sets and fire control measures.
The **Member Secretary** or *IEC Coordinator* will:

- Get the master copy of research study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum of , the following documents:
- Original applications of projects for initial review and any updates received during the study.
- *Investigator's* brochures or similar documents.
- Agreements signed by appropriate authorities, such as: Clinical trial agreement, Insurance document.
- Photocopies of statutory permissions as applicable.
- Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
- Approval letters for protocol & protocol related documents.
- Adverse experience reports or IND safety reports received/*SAE reports*.
- Continuing review reports.
- Copy of all original letters received from the *Principal Investigator*.
- Copy of all correspondence letters sent to the investigator.
- The name of the *Sponsor/Principal Investigator*.
- The protocol number assigned by the *IEC* **Member Secretary** or *IEC Coordinator*.
- The Sponsor details with address and contact phone/e-mail id of *contact* person, protocol number, investigator name (with address, e-mail, telephone and fax) and title of the study.
- The application form of *IEC*, *Protocol, Case Record Form, Investigator's Brochure (IB) (drug studies), Informed Consent Documents with translations in the relevant language of Hindi, advertising material and recruitment procedures, investigator bio-data, any other material submitted by the Investigator.*
- Initial Approval with final version of all documents (protocol, ICD, CFR, etc.).
- Revision/Amendments.
- Approval of amended protocol/protocol related documents.
- Adverse Events.
- Continuing Review, if applicable.

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- Final Report

10.2 Maintenance of Active Study Files

- Combine related documents of the approved research study files appropriately.
- Attach an identity label to the package.
- Keep all active and potential study packages in a secure file cabinet.
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the *IEC*.
- Send all closed study files to archives.
- Send all closed study files for guidelines as per *IEC SOP*.

11.0 Archival and Retrieval

The *process of archival* implies instructions for storing inactive study files and administrative documents in a secure manner for a duration as per regulatory requirements while maintaining access for review by auditor's and inspectors. Copying of files and related documents of *IEC* approved research studies by authorized representatives of national and international regulatory authority is allowed.

The correspondence between the *IEC and PI/Study Team* and other relevant records (response letter, minutes of meeting, composition etc.) are retained for a minimum period of 5 years after completion of the trial.

11.1. Record Keeping and Archiving

The *IEC* **Member Secretary** and *Members* review the final report of the research study.

The **Member Secretary** or *IEC Coordinator* should

- Remove the contents of the entire file from the archive study filing area.
- Verify that all documents are present in an organised manner.
- Shift it to a cupboard wherein all files, to be archived, are placed.

The **Member Secretary** or *IEC Coordinator* will hold the files of multi-centre studies, until all study sites are closed.

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The **Member Secretary** or *IEC Coordinator* maintains past *IEC Membership* information as well as archive administrative documents as permanent records. The documents will be archived as per national and international guidelines.

The documents of *IEC* are archived at the following address and can be made available for any regulatory authority assessment (if at least 3-working days' notice is provided to the *IEC*):

The Archival Room
Office of Ethics Committee
Mahatma Gandhi Medical College and Hospital,
Jaipur-302022.

11.2 Retrieval of Documents

- The retrieval of documents can only be done with a request form signed and dated by the *IEC* **Chairperson** or *IEC* **Member Secretary**.
- The requestor must also sign and date the request letter.
- The **Member Secretary** or *IEC Coordinator* retrieves archived documents and returns thefile back to its place.
- The **Member Secretary** or *IEC Coordinator* will also record, sign and date when the document has been returned and kept.

12.0 Dealing with Participants/Patients/Any Relevant personnel's Requests and Complaints

The *IEC* considers protection of the rights and welfare of Human Subjects participating in clinical research approved by the *HIEC* of singular relevance and is its primary responsibility, Informed Consent documents reviewed by the *HIEC* contains the statement, "Questions regarding the queries regarding rights of a participant/patient may be addressed to the *IEC*, **Member Secretary**, with the *IEC address and phone number.*

12.1 Responsibilities of IEC Members

If there is any complaint received from participants/patients /any relevant personnel, Member Secretary/Chairperson shall initiate a process of identifying and addressing any

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injustice that has occurred. The study participant subject can contact the *IEC* **Chairperson** or **Member Secretary** for any request/complaints or query as contact details of *IEC* **Chairperson** and **Member Secretary** are mentioned on *IEC* approved *Informed Consent Documents*. Alternately, the *IEC Members* may contact the patient randomly to understand if there are any patient grievances.

12.2 Procedure for Resolving Requests and Complaints

- The query/complaint will be recorded in the request record form.
- The **Member Secretary** will inform the **Chairperson** about the query/complaint received.
- If any information is requested from the *IEC Office*, the **Chairperson** or **Member Secretary** will share the information, as per regulatory norms.
- If there is any complaint received from participants/patients/any relevant personnel, **Chairperson/Member Secretary** shall initiate a process of identifying and addressing any injustice that has occurred.
- The **Chairperson** or **Member Secretary** shall decide to consider the matter for discussion at a full *IEC Meeting* or call an *emergency meeting* of 2 or more *IEC Members* for discussion or to appoint a sub-committee of 2 or more *IEC Members* for enquiry in order to resolve the matter.
- The **Chairperson** or **Member Secretary/designated IEC Member** will study the situation and will mediate a dialogue between the *Complainant* and the *Investigator* to address the issue. If needed, **Member Secretary** will call for relevant information and documents from the *Investigator*.
- The **Chairperson** or **Member Secretary/designated IEC Member** shall study the entire issue to appreciate the facts of the issue involved and if required shall interview *Complainant* and *Investigator/Investigator Study Team Members* individually. The final decision will be informed to the *Complainant* by the *Secretariat*.
- The information inclusive of any action taken or follow-up will be recorded in the form that would be signed, validated and dated. Any action taken and the outcome shall be communicated all *IEC Members* in the forthcoming scheduled *IEC Meeting*.
- The request document and record form will be duly filled in the 'response' file by the **Member Secretary**/*Administrative staff*.
- A copy of the same will be kept in the respective study file.

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13.0 Policy of Communications with Different Stakeholders

The *Institutional Ethics Committee (IEC)* communicates with different following stakeholders as per laid down norms of respective regulatory bodies:

- *The Principal Investigator/Study Team Designee.*
- *CDSCO, DCGI, New Delhi.*
- **The Principal and Controller,** *Mahatma Gandhi Medical College and Hospital, Jaipur-302022.*
- *The Sponsor.*
- *The Study Participants.*

13.1 Principal Investigator

The *IEC* writes to *Principal Investigator (PI)* or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- The *Study Project Initial Dossier and Amendments, Approvals/Dis-Approval letter/Query letters.*
- *The reply to Serious Adverse Event (SAE) notification.*
- *The Opinion of IEC analysis and compensation of study injury/death.*
- *The response to Protocol Deviation/Violation/Waiver.*
- *The response to Continuing Review/Study Completion Report.*
- *The study termination letter.*

13.2 CDSCO, DCGI, New Delhi

The *IEC* writes to *CDSCO, DCGI, New Delhi* or email regarding following mentioned communications but not limited to, whenever deemed necessary:

- *The Opinion of IEC analysis and compensation of study injury/death.*
- *The study termination letter.*
- *The issues with Investigators or different stakeholders involved.*
- *The recommendations on DCGI approved studies (if necessary).*
- *The Ethics Committee Registration communications.*

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13.3 The Head of Institute

The *IEC* writers or emails to **The Principal and Controller**, *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* regarding following mentioned communications but not limited to, whenever deemed necessary:

- *Annual Reports of IEC.*
- *Sharing amended SOP for final acceptance.*
- *Any issues in IEC functioning.*
- *IEC Requirements*

13.4 Sponsor

The *IEC* write or emails regarding following mentioned communications but not limited to, whenever deemed necessary:

- *The response to queries raised.*
- *The confirmation of free medical management and compensation in applicable cases (if deemed necessary).*

13.5 Study Participants

The *IEC* write or emails regarding following mentioned communications but not limited to, whenever deemed necessary:

- *The reply for complaints.*
- *The reply to request for any information requested from IEC Office.*

14.0 Institutional Ethics Committee (IEC) Self-Assessment

14.1 Purpose

The activities and quality of working of the *IEC needs to be self-assessed* in order to ensure that the *IEC* is working along the laid down stipulations of respective regulatory bodies.

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Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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14.2 Overall IEC Self-Assessment

The **Chairperson** designated *IEC Member* shall conduct *self-assessment* of *IEC on an annual basis.*

14.3 The IEC Members and Secretariat Self-Assessment

Two periodic reviews per year shall be conducted as mentioned below:

- Self-evaluation of **Chairperson.**
- The **IEC Members/Member Secretary** assessment will be done by the **Chairperson** who will communicate the individual feedback, respectively through the *IEC Secretariat.*
- The *IEC Administrative Staff* would be assessed by the **Member Secretary.**

14.4 The IEC Self-Assessment Procedure

- The **Member Secretary** will present the *self-assessment reports of all IEC Members* in subsequent scheduled *IEC Meeting* and any recommendations, if any, will be implemented, accordingly.
- The *IEC* conducts *self-evaluation* in terms of appropriateness of composition, attendance and resources with the *IEC.*
- The *IEC* will do a *Root Cause Analysis (RCA)* to identify if there is a process failure or a system failure.
- There should be a minimum of two periodic reviews per year.

15.0 Records or Reports

15.1 The Institutional Ethics Committee (IEC)

All documents and communication of the *IEC* related to clinical drug trials are filed and stored in a safe and secure place maintaining strict confidentiality during access and retrieval procedure.

The following documents are stored:

- *The Composition of IEC.*
- *The CV of all IEC Members.*

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- *The SOP of IEC.*
- *The New Drugs and Clinical Trials Rules (NDCT), 2019 of CDSCO, DCGI, ICMR Guidelines of 2017 on Biomedical Research on Human Participant, Indian Good Clinical Practices Guidelines, ICH-GCP guidelines.*
- *The copies of Protocol, Investigator Brochure, Informed Consent Form, Regulatory Approvals and other relevant documents submitted to IEC.*
- *All correspondence with IEC Members and Investigators regarding applications, decision and follow-up.*
- *The minutes of IEC Meetings duly signed by* ***Chairperson*** *and* ***Member Secretary.***
- *The copies of decisions communicated to the applicants.*
- *The record of all notification issued for premature termination of a study with a summary of the reasons.*
- *All safety reports submitted to IEC and final report of the study.*

15.2 The Investigator/Sponsor

The investigator submits all safety reports to *IEC* within the specified timelines. All amendments to the *Protocol or other essential trial documents* are approved by the *IEC* before they are implemented. All *protocol deviations* are notified to *IEC* within 7 working days after they come into notice. In case of premature termination of the clinical trial at site, the sponsor intimates in writing to the *IEC* and also specifies the reasons for the termination.

15.3 Insurance

The sponsor submits a copy of the *Insurance* to the *IEC* that need to renewed as applicable and the *IEC Office* needs to ensure the validity of the *Insurance,* so submitted.

15.4 Undertaking by Investigator

The *Investigator* submit an undertaking to above by the stipulations of regulatory bodies, both national and international.

15.5 Research Misconduct

The Institute, *MGMCH, Jaipur* is responsible for promoting research integrity within the Institute and oversees investigations of *Research Misconduct* allegations, and make final decisions on findings of *Research Misconduct*. The *IEC, MGMCH, Jaipur* has evolved a structured program to

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deal with the hazards and menace of *Research Misconduct* and has evolved policies and mechanisms to define *Research Misconduct,* to establish procedures for reporting and investigating *Research Misconduct* and to protect both those who report alleged *Research Misconduct* and those accused of *Research Misconduct. The primary responsibility for reporting and investigating allegations of Research Misconduct lies with the respective researchers and the Institute, based on the premise that research is a profession that should regulate its own conduct.*
Research Misconduct [a non-compliance of *International Committee for Harmonisation-Good Clinical Practice (ICH-GCP)*]has been defined as "*fabrication (making up of data or results and recording or reporting them), falsification (changing research materials, equipment or processes or altering or omitting data or results that the research record does not accurately reflect the research findings), plagiarism (using another person's ideas, processes, results or words without giving appropriate credit) or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research*".
Research Misconduct does not include honest error or differences of opinion and it does not apply to authorship disputes unless they involve *plagiarism. Research Misconduct* is applicable to all types of researches whether funded (intramurally or extramurally) or self-initiated. However, non-compliance with policies and procedures for protection of human research subjects, though reportable to *Institutional Ethics Committee* of *Mahatma Gandhi Medical College and Hospitals, Jaipur-302022* is not considered to *Research Misconduct.* The records maintained by *HIEC* during the investigation of an allegation of *Research Misconduct* are exempt from disclosure under Right to Information Act to the extent permitted by prevailing laws and regulations.

The term **Fraud** has often been used to describe *dishonesty in research.* However, this term is more aptly used to describe illegal, deceptive financial practices. Behaviour that destroys the integrity of the research record through fabrication, falsification, or plagiarism is most aptly termed *Research Misconduct.*

The research institutions need to foster an environment that discourages all research misconduct, use laid-down procedures for receiving and investigating reports of *Research Misconduct*, inform *Scientific Committees* [*Departmental Research Committee (DRC)* and *HIEC*] and respective administration section of the Institute of the procedures of responding to allegations of *Research Misconduct*, take immediate and appropriate action when *Research Misconduct* is suspected or alleged to have occurred at the Institution, investigate and rule on suspicions or allegations of *Research Misconduct* and report both the start of and results of a formal investigation into an allegation of *Research Misconduct* to concerned authorities.

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Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMCH, Jaipur

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