Institutional Ethics Committee
Mahatma Gandhi University of Medical Sciences & Technology
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

16.0 Annexure

Annexure 16.1: Confidentiality & Conflict of Interest Document for IEC Members

In recognition of the fact, that I, (name and designation) ....herein referred to as the —Undersigned, have been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/territory/community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;
The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets (—information‖) in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that the performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but I have faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC. I will disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee and abstain from participation in discussions or recommendations in respect of such proposals.
Examples of conflict of interest cases may be any of the following:
A member is involved in a potentially competing research program.
Access to funding or intellectual information may provide an unfair competitive advantage.
A member's personal biases may interfere with his or her impartial judgment.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (—Confidential Information‖). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information

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(including any agenda items) to the Bioethics cell upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, ... have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature: _____
Name: _____
Date: _____

Signatory of SOP approval
Member Secretary, ethics committee

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Annexure 16.2: Confidentiality Document Form for Independent Consultants

I,.....,(name and designation) as a non-member of IEC understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Signature: _____
Name: _____
Date: _____

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Annexure 16.3: Invitation to Attend a Meeting as Independent Consultant

To,

_____
_____
_____

Sub: Invitation to attend Institutional Ethics Committee meeting

Sir/Madam,

The Chairman IEC has nominated you as an independent consultant/observer to evaluate a research protocol submitted to the Institutional Ethics Committee for approval.

You are requested to attend the meeting of IEC on .....at.....and to provide written opinion regarding the assigned research proposal (IEC code no ..... and title of project.....). You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal. Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the *Ethics Committee, Mahatma Gandhi Medical College and Hospital, Jaipur* after the meeting.

Yours faithfully,

Signature of the Member Secretary _____ **Date** _____
Name of the Member Secretary _____

Enclosures:
1. Research protocol
2. Confidentiality document

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Annexure 16.4: Invitation to Attend a Meeting as Observer

To,

_____
_____
_____

Sub: Invitation to attend Institutional Ethics Committee meeting.

Sir/Madam,

The Chairman IEC has invited you as an independent observer to see functioning of the Institutional Ethics Committee meeting.

You are requested to attend the meeting of IEC on .....at..... You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Yours faithfully,

Signature of the Member Secretary _____ **Date** _____

Name of the Member Secretary _____

Enclosures:

1. Confidentiality document

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Annexure 16.5: Confidentiality Document Form for Observer Attendees to EC, Mahatma Gandhi Medical College and Hospital, Jaipur Meetings

I..... ..... (Name and designation) understand that I am invited to attend the *IEC meeting* scheduled on.....at.....am/pm as an Observer. In the course of the meeting of the IEC some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

Signature: .....
Name: .....
Date: .....

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Annexure 16.6: Curriculum Vitae Format

Personal Information

Name:	
Full Site Address: (incl. postal code)	
E-mail:	**Phone number:**

Name of Granting Institution	Location (City, Country)	Degree	Year Obtained

Current Position (Affiliation to study site)

Title:	**Start Date** (YYYY):
Address:	

Experience/Current and Previous Positions (*in chronological order)

Title	Address (Institute Name, Location)	From (YYYY)	To (YYYY)

Ethical Committee Experience

Start Date	Role in EC

ICH-GCP Training
Have you attended a course in ICH-GCP Training ☐Yes ☐No

Signature:	**Date:** (DD-MMM-YYYY)

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Annexure 16.7: Ethics Committee Membership List

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 Voliara, 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
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
		Member (Lay Person)	Non-Affiliate

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14	Smt. Preeti Soni, Lay Person from Community, Jaipur.		
15	Dr. (Mrs.) Lata Joshi, Lay Person from Community, Jaipur.	Member (Lay Person)	Non-Affiliate

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Annexure 16.8: EC Submission Letter format
(On letter head of Institute/Personal)

Date:
To

Chairman / Member secretary
Ethics Committee
Mahatma Gandhi Medical College and Hospital, Jaipur-302022

Reference: Study number: Study title----------
Subject: Institutional Ethics Committee Submission of following documents for the conduct of above referenced study at **Mahatma Gandhi Medical College and Hospital, Jaipur.**
Dear Sir / madam
The referenced study has been discussed with me by the representatives of Contract Research Organization/Sponsor. I have considered the proposal and feel that the recruitment for this clinical trial can be met at our hospital. The Inclusion /Exclusion criteria and other study–related details are described in the referenced Protocol. A study team has been appointed and will work on the conduct of study according to the ICH GCP guidelines, Indian GCP guidelines and national and international guidelines under my direction, as I shall be working as the Principal Investigator for the referenced protocol.
I am submitting --- copies of the following documents for the above-mentioned clinical study for Institutional Ethics Committee Review:

- Protocol ----------
- Investigator's Brochure- Version -- Dated -----
- Informed Consent Form in English and other regional languages.
- Case Report Form- ------
- Questionnaire or scales used in the
- Patient Emergency Card- in English and other regional languages if applicable.
- Regulatory – DCGI – Submission letter for approval of study -Dated ------
- Regulatory –DCGI – Study approval Letter – Dated --------
- Import Drug License –Dated ----------
- NOC for biological sample – Dated ---------
- IND Safety Report – Date ----- If Applicable.
- Project proposal-12 copies

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- Curriculum Vitae and MRC (If Applicable) Investigators
- Financial Disclosure of Investigator
- Copy of Advertisements/Information brochures
- Copy of Insurance Policy
- Copy of Clinical trial agreement
- Copy of IEC Proforma
- Copy of PI undertaking
- Copy of NOC from Institution.
- Copy of MRC and GCP Certificate

I wish to assure IEC that Initiation of study and enrolment of patients will commence only after receiving IEC approval letter as well as required regulatory approvals.
The study will be conducted in accordance with the Indian GCP, ICH GCP guidelines and national and international regulations.
Voluntary consent (written consent) will be obtained from each participating subject/ relative, on the IEC approved Informed Consent form, prior to start of any protocol related procedures on the patients, audio-video consenting (if applicable) shall be carried out as per national regulations.
May I request you to review and opine on the aforementioned proposal & enclosed study documents, for the conduct of the study in our Centre?
Please revert to me should you wish further information or any clarification.
Thank you.

Dr. ----------
Principal Investigator

Protocol: ----------

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Annexure 16.9: Project Submission Proforma

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Board Board (IEC) for initial review only:
(For attachment to each copy of the proposal)
Code No. of IEC: - ----------
(To be filled by IEC Member Secretary/Admin Manager/IEC coordinator)
Proposal Title----------

A. Investigators Information:

	Principal Investigator	Co-Investigator	Co-Investigator
Name			
Qualification			
Designation			
Mobile			
Landline			
Email			
Sign			

Note: Please attach Curriculum Vitae of Principal Investigator. The investigator should sign their CV.

B) Sponsor Information:

Sponsor Company	Name	Contact No.: & Address
Indian		
International:		

C) **Study Information** (Note: Circle whatever applicable): -
1. Type of study: - Epidemiological/Clinical/Single Center/Multicentric

2. Clinical Trials (Drug/Vaccines/Device/Herbal Remedies):

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i. Does the study involve use of		
Drugs	Devices	Vaccines
Other Specify:		None

ii) Is it approved and marketed			
India	UK & Europe	USA	Other

iii) Does it involve a change in use, dosage, route, of administration?	Yes	No
If yes, whether DCGI's/Any other Regulatory Authority's Permission obtained	Yes	No
If yes, copy of permission attached	Yes	No

iv) Is it an Investigational New Drug		Yes		No	
If Yes provide following information					
Investigator's Brochure enclosed		Yes		No	
Preclinical studies data available		Yes		No	
Clinical studies data available		Yes		No	
Clinical study	Phase I	Phase II	Phase III	Phase IV	NA
DCGI's permission obtained		Yes		No	
If yes, copy of letter enclosed		Yes		No	

3. Brief description of the proposal (Maximum 500 words):

Aim & Objectives----------

Justification for study ----------

Methodology----------

Potential risks and benefits ----------

Outcome measures ----------

Statistical analysis ----------

National significance ----------

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4. Subject Selection: -

i) Number Of Subjects: ----------		
ii) Duration of study: ----------		
iii) Duration Participant: ----------		
iv) Would Participant from both sexes be recruited	Yes	No
If No, Specify the reason.		
v) Inclusion/Exclusion criteria given	Yes	No
vi) Type of subjects	Volunteers	Patients
vii) Vulnerable subjects	Yes	No

If Yes (Circle: Pregnant Women, Children, Elderly, Fetus, Illiterate, Handicapped Terminally ill, Seriously ill, Mentally Challenged Economically & socially backward Any other----------		
viii) Special group subjects	Yes	No
If Yes (Circle: Captives, Institutionalized, Employees, Students, Nurses/Dependent Armed Forces, Any Other		

5. Privacy and confidentiality:

Study Involves		
Direct Identifiers	Indirect Identifiers/Coded	Completely, Anonymized /Delinked
Confidential handling of data by staff	Yes	No

6. Will any advertising be done for recruitment of Subjects?

(Posters, flyers, brochure, websites – if so attach a copy)	Yes	No

7. Is there compensation for injury?

Compensation for injury		Yes (by whom)	No
Sponsor	Investigator	Insurance Company	Any Other

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8. Use of biological/hazardous materials:

i. Use of fetal tissue or abortus. If yes provide details	Yes	No
ii. Use of organs or body fluids. If yes provide details	Yes	No
iii. Use of recombinant/gene therapy products	Yes	No
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? If yes, give details and address of collaborators	Yes	No
a. Sample will be sent abroad because (Circle) Facility not available in India Facility in India inaccessible Facility available but not being accessed If so, reasons		
b. Has necessary clearance been obtained	Yes	No

9. Risks & benefits:

i. Is the risk reasonable compared to the anticipated benefits to subjects/community/country?	Yes	No
ii. Is there physical/social/psychological risk/discomfort?	Yes	No
If yes: Minimal or no risk		
More than minimum risk High risk		
iii. Is there benefit to the subject?	Yes	No
	Direct	Indirect
iv. Is there benefit to the society	Yes	No

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10. Consent:

Written, Oral, Audio-Visual

i. Patient Information Sheet attached:	Yes	No
Tick the included elements: 1. Understandable language 2. Alternatives to participation 3. Statement that study involves research 4. Confidentiality of records 5. Sponsor of study 6. Contact information of Investigator 7. Purpose and procedures 8. Statement that consent is voluntary 9. Risks & discomforts 10. Right to withdraw Consent 11. Benefits 12. Compensation for participation 13. Compensation for study related injury 14. Contact Information IEC		
ii. Translation of information sheet in local Language If Yes which languages: ----------	Yes	No
iii. Back translation of local languages in English for review	Yes	No
iv. Who will obtain consent? PI, Co-PI, Nurse/Counselor, Research Staff, Any Other ----------		
v. If written consent is not obtained, give reasons:		

11. Data monitoring:

i. Is there a data & safety monitoring board/Board (DSMB)?	Yes	No
ii. Is there a plan for interim analysis of data	Yes	No
iii. Is there a plan for reporting of adverse events?	Yes	No
If yes, reporting will be done to: Sponsor, IEC, DSMB		

12. Do you have conflict of interest?

i. Do you have conflict of interest?	Yes	No
Financial or Non-financial Please specify:		

13. Hospital Support in terms of:

- Manpower
- Financial
- Sundry
- Space

14. Budget Allocation Details:

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D) Investigators Declaration:

1. The investigators agree that the grant money will be spent in accordance with the budget proposal only.
2. The investigators will declare any financial gain from the commercial sponsor and any conflict of interest in the drug or product by way of consultations, shareholding, etc.
3. The study documents will be made available to members of the IEC any time for random verification and monitoring. The study documents must ensure archived for 15 years post study close out or until the sponsor confirms that the records are no longer required; whichever is earlier.
4. All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc. will be first presented to *Ethics Committee,* Mahatma Gandhi Medical College and Hospital, Jaipur-302022 before they are released or presented elsewhere.

E) Financial Disclosure Form for Researchers

Project entitled: .....
Name of PI:

1. Employment or Leadership Position

Check yes if you or an immediate family member currently holds any full-time or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

2. Consultant or Advisory Role

Check yes if you or an immediate family member holds or has held any consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

3. Stock Ownership

Check yes if you or an immediate family member currently holds any ownership interest in any company (publicly traded or privately held) that has an investment, licensing, or other commercial interest in the research study under consideration.

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☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

Check yes if you or an immediate family member has been paid directly any honoraria (reasonable payments for specific speeches, seminar presentations, or appearances) from an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

5. Research Funding

Check yes if you or an immediate family member currently conducts any clinical research project(s) funded, in whole or in part, or has received any post study awards by an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes☐ No If yes, amount received in last 12 months in Rs. _____

6. Patent or Royalty interests

Check yes if you or an immediate family member has received any patent or royalty from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

7. Other Remuneration

Check yes if you or an immediate family member has received any trips, travel, gifts, or other in-kind payments at any point from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

I hereby agree to recuse myself from any deliberations and actions involved in the approval or re-approval of a protocol for which I have a real or apparent conflict of interest, and from discussions of these matters unless my presence for discussions is requested by the IEC Chair.

☐ I hereby declare that I have no conflict of interest in my project.
☐ I have above conflict of interest:

_____ _____

Signature of PI Date

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F). Budget Sheet for the Proposed Study

1	Title of the Project:		
2	Principal Investigator		
3	Designation and address of the PI		
4	Source of funding		
	Intramural		
	Extramural		
	a) Government (please specify)	☐ Central ☐ State ☐ Local	
	b) Private Foundation: (please specify)	☐ Indian ☐ Foreign	
	c) Industry: (please specify)	☐ Private ☐ Public ☐ Other	
	• d) Other:		
	Pharma sponsored	☐ Indian ☐ Foreign	
	Address, phone, fax. E-mail of sponsor with the name of the contact person		
	No funding required		
5		Total Budget for the entire project in Rs.	
6		Duration of the Project in months	
7		Proposed date of starting the project	
8		Direct payments to investigators, if any	
9		Any other benefits to the investigators	
10	Name of PI:	Signature:	Date

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Detailed Budget for the Proposed Study*

1. Source of funding	**Please specify**			
Items	1st Year	2nd Year	3rd Year	Total
2. Salaries-personnel (Numbers)				
Doctor / Post-Doc (Research Fellow)				
Research Nurse				
Data operator				
Any other specify				
3.Equipment and Hardware-kindly specify				
-				
-				
4. Drugs and Consumables				
-				
-				
5. Clinical Investigations				
-				
-				
6. Hospitalization				
-				
-				
7.Travel expenditure for investigators				
-				
-				
8. Travel expenditure for Research Participant and one attendant				
9. Honorarium to doctors/technicians				
10. Insurance				
i. for investigators				

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ii. any unforeseen, accidental trial related injury				
11. Any other expenditures				
12.Miscellaneous (<5% of budget)				
13. Grand Total				
Name of PI:	**Signature:**		**Date**	

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.
- Please specify year-wise total in grand total column

Project No.	
Trial Register No.	
Project Title (To be filled by PI)	----
Revised Title if any (To be filled by IEC)	
Principal Investigator	----

Check List for attached Documents: (Tick)

- Protocol Submission Proforma
- Submission letter
- Final Copy of Protocol with Version No. and Date
- Final Copy of Investigators Brochure with Version No. and Date
- Copy of Informed Consent Form (English) with Version No. and Date
- Copy of the Patient Information sheet (English) with Version No. and Date
- Copy of Informed Consent Form (Other Languages) with Version No. and Date (Please List the Languages)
- Copy of the Patient Information sheet (Other Languages) with Version No. and Date (Please List the Languages)
- Translation & Back Translation Certificate
- Undertaking from the Sponsor regarding Compensation as per GS. R. 53 E dated 30 Jan 2013
- Undertaking by the Investigator
- Copy of the Case Report Form
- Submission/Approval Letter from the Drugs Controller General of India
- Copy of Clinical Trial Agreement between the Investigator & Sponsor, if applicable
- Current signed CV of the Principal Investigator
- Copy of Insurance and Indemnification Policy for the investigator /institution
- Global Regulatory approvals, if available

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- IEC approvals from other sites, if available
- EC Fees (as per EC - SOP) in favor of "***Mahatma Gandhi University of Medical Sciences and Technology*, Jaipur 302022**", Payable at **Jaipur**
- Compensation scheme for patients
- Proposed financial / drug benefits to the patient
- Declaration by Investigator stating not more than 7 ongoing studies
- Specify if any other document enclosed

Signature of PI / Co-investigator

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Annexure 16.10: Document Receipt Form

Document Receipt Form

Study Number	
Submitted date:	
Type of Submission:	☐ Initial Review ☐ Continuing Review of Approved Protocols
Protocol Title:	
Principal Investigator:	
Mode of submission: ☐ Post ☐ E-submission ☐ in Person	
Type of document:	

Checklist to assess the projects before they are submitted to IEC review

Item No.	Mandatory Documents	Yes	No	NA
1	Protocol Submission Proforma			
2	Submission letter			
3	Final Copy of Protocol with Version No. and Date			
4	Final Copy of Investigators Brochure with Version No. and Date			
5	Copy of Informed Consent Form (English) with Version No. and Date			
6	Copy of the Patient Information sheet (English) with Version No. and Date			
7	Copy of Informed Consent Form (Other Languages) with Version No. and Date (Please List the Languages)			
8	Copy of the Patient Information sheet (Other Languages) with Version No. and Date (Please List the Languages)			
9	Translation & Back Translation Certificate			
10	Undertaking from the Sponsor regarding Compensation as per GS. R. 53 E dated 30 Jan 2013			
11	Undertaking by the Investigator			
12	Copy of the Case Report Form			
13	Submission/Approval Letter from the Drugs Controller General of India			

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14	Copy of Clinical Trial Agreement between the Investigator & Sponsor, if applicable			
15	Current signed CV of the Principal Investigator			
16	Copy of Insurance and Indemnification Policy for the investigator /institution			
17	Global Regulatory approvals, if available			
18	IEC approvals from other sites, if available			
19	EC Fees (as per EC - SOP) in favor of '*Mahatma Gandhi University of Medical Sciences and Technology*, **Jaipur-302022**', Payable at **Jaipur**			
20	Compensation scheme for patients			
21	Proposed financial / drug benefits to the patient			
22	Declaration by Investigator stating not more than 7 ongoing studies			
23	Specify if any other document enclosed			

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Annexure 16.11: Informed Consent Form Elements Checklist

(Based on *New Drugs and Clinical Trials Rules, 2019*)

All Informed Consent Forms and Patient Information Sheets must have the following essential elements:

Essential Elements	Please tick ( )
Statement that the study involves research and explanation of the purpose of the research	
Expected duration of the Subject's participation	
Description of the procedures to be followed, including all invasive procedures & others	
Description of any reasonably foreseeable risks or discomforts to the Subject	
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	
Disclosure of specific appropriate alternative procedures or therapies available to the subject.	
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	
Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)	
Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury and/or death	
An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury	
The anticipated prorated payment, if any, to the Subject for participating in the trial	
Subject's responsibilities on participation in the trial	
Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled	
Any other pertinent information	

Other Requirements are as enlisted below:

Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent	
Additional costs to the subject that may result from participation in the study	
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.	

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Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided	
A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable	
Approximate number of Subjects enrolled in the study	
Space for Subject's details: DOB, Age, Address, Qualification, occupation, Annual Income of Subject, name, address and relation of Nominee with subject	
At the end of ICF clearly state that "(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his / her attendant)	

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Annexure 16.12: Informed Consent Form Template

Part – 1: Participant Information Sheet

Principal Investigator: Dr. _____
Department of ....
Mahatma Gandhi Medical College and Hospital, Jaipur.
Study Title: _____

1. Introduction:

You are invited to participate in a study/research project titled_____.
I am, Dr..... in department ..... at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022*. Here We are doing study on ..... disease, which is very common in this country. Before you agree to participate in this study, you need to know the risks and benefits so you can make an informed decision. This process is known as "informed consent".
This consent form tells you about the study that you may wish to join. Please read the information carefully and discuss it with anyone you want. If you have questions, please ask the Study Doctor or study staff to answer them.
Your participation in this research study is strictly voluntary. You may decide not to participate, or you may withdraw from the study at any time without any penalty or loss of benefits to which you are entitled at this site. In case you decide to participate in the study and then choose to step out at a later time, no new information will be collected post your withdrawal decision; however, any previously collected information will be utilized in the study.
Your Study Doctor may withdraw you from the study at any time should he/she feel it is in your best interest.

2. Purpose of the Study:

The purpose of this study is to_____
Briefly explain in lay language- the background of the problem, the need & purpose of the study, use simple self-explanatory language / words that can be understood by 7th Std student.

3. Participant selection

You have been asked to participate as you meet the eligibility criteria for the study. (explain eligibility criteria in layman language, Ex. Patients of 18 years old and above, of either gender, diagnosed with ---- ---------- would be eligible to participate in the study .....).

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4. Procedures & Type of Study Intervention:

The study will involve your answering a few questions about yourself and going through your clinical and laboratory findings to ascertain the possibility of ---------- (Disease). I will provide you information and invite you to be part of the study. There won't be any additional study procedures apart from routinely required.

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental. Participants should know what to expect and what is expected of them.

In the first visit, we will also ask you a few questions about your general health. You will be asked at ---- visits to complete questionnaires about your general health, your ---------- (Disease), your pain, fatigue, general condition and your experience with the medication.

Explain in brief about follow up visits (If Any)

Include a statement about the time commitments of the study for the participant including both the duration of the study and follow-up (if relevant). For example, in total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the study will be completed.

Mention about the questionnaire/ interview, in case these are a part of the study procedure and provide all details - about its timing i.e., when it would be administered / conducted, purpose and what will be asked / information collected through these. Also mention if the participants have an option to not answer certain questions in the questionnaire / interview.

Briefly state the type of intervention that will be undertaken. For example, the study involves a vaccine, an interview, a biopsy or a series of finger pricks. If there is no intervention, please mention there is no intervention.

5. Duration of participation.

It should include time period from first visit (consenting visit) to last follow up visit of the patient which would be at -------- weeks/months/years.

6. Your responsibilities

If you decide to participate in the study, you are required to follow up regularly, For Ex. At 3 weeks, 3 months, 6 months …….. These are routine clinical visits.

You need to answer few questions regarding your symptoms and allow us for clinical examination and to go through all the investigations done in the past or at the time of the current visit.

7. Side Effects

There are no side effects related to your participation in the study.

8. Risks

There will not be any additional risk other than those observed in routine care and procedure.

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What if something goes wrong?

The sponsor has taken out insurance coverage in accordance with the legal requirements. During the study, any other medical treatment except for emergency situations must always be agreed beforehand with the study doctor. If personal injury is suspected to have occurred as a result of involvement in this study, your study doctor must be informed immediately so that he/she can inform the sponsoring company.

The insurance policy taken by sponsor covers any claim for medical care or compensation due to injury or death related to the study, wherein such medical care is required or injury or death has resulted from administration of any study drug or any other procedure carried out in accordance with the protocol for the study drug or any other procedure carried out in accordance with the protocol for the study or due to negligence of the sponsor.

In an event of an injury occurring to you because of your participation into this clinical trial, you shall be given free medical management as long as required or till such time it is established that the injury is unrelated to the trial; whichever is earlier.

You shall be entitled for financial compensation as per the orders of the Licensing Authority.

In case of death caused due to participation into this clinical trial, your nominee would be entitled for financial compensation as per the orders of the Licensing Authority.

9. Benefits

There may not be any direct benefit for you but your participation is likely to help us find the answer to the study question. There may not be any benefit to the society at this stage of the study, but future generations are likely to benefit because the information provided will help us get insight into

---

----------(Ex ...the spectrum of clinical manifestations of scleroderma and the association between skin and lung manifestations)

10. Reimbursements

As all visits are as per routine care, no travel reimbursement will be given. There won't be any kind reimbursement as study participant does not incur any additional cost by participating in the study.

11. Confidentiality and who will review data and have access to data.

Unless required by law, your name will not be disclosed outside your treating clinic/hospital. Your name will be available only to the following people or agencies: the Study Doctor and staff; and authorized representatives of the Study Doctor; ethics committees, health authority inspectors, such as (but not limited to) the Drug Controller General of India. Authorized study monitors and auditors.

The above-mentioned individuals will use the personal information collected as part of this study, including your medical records ("Study Information") to check that the study is conducted correctly and to ensure the accuracy of the Study Information. These people are all obligated to maintain confidentiality by the nature of their work or are bound by confidentiality agreements.

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While participating in this study, the Study Doctor will replace your name with a special code that identifies you. This code, along with your Study Information, will be used for the study purposes as mentioned above. Also, this code will not be linked to hospital records.

12. Alternatives to participating

This section is to be included only if the study involves administration of investigational drugs or new therapeutic procedures. It is important to explain and describe the established standard of care.
Example: If you do not wish your child to take part in the research, your child will be provided with the established standard.treatment available at the hospital.

13. Sharing the Information and Results

The knowledge that we get from doing this study may be published so other interested people may learn from our study.

14. Who to Contact

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
Investigator ….. (Name and Contact number)
This proposal has been reviewed and approved by Institutional Ethics Committee (IEC) which is a committee whose task is to make sure that study participants are protected from harm. If you wish to find about more about the IEC, following are communication details.

Mailing Address IEC:
Ethics Committee,
Sitapura
Mahatma Gandhi Medical College and Hospital, Jaipur-302022.

Chairperson of IEC: Professor (Dr.) S. C. Lodha
Ethics Committee,
Sitapura
Mahatma Gandhi Medical College and Hospital, Jaipur-302022.
Mobile:
E mail:

You will be given a copy of the Participant Information Sheet & signed Informed Consent Document.

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Part 2: Informed Consent Form

Participant's Initials: _____ Participant's Name: _____

Date of Birth / Age: _____

Please Initial Box

i. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

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

iii. I understand that the study investigator and study team, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand my identity will not be revealed in any information which may get published. [ ] [ ]

iv. I agree not to restrict the use of any data or results that arise from this study provide such a use is only for scientific purpose(s). [ ]

v. I agree to take part in the above study. [ ]

vi. I am aware that it has been agreed by the sponsor that in case of study related injury of Death, the *Sponsor* i.e., (*Name of Sponsor*), will provide complete *Medical Care as well as Compensation* for the Injury to the Individual and in case of death to his legal heirs. [ ]

Name of the parent	Sign/Thumb Impression	Date
Name of the LAR (Legally Acceptable Representative)	Sign/Thumb Impression	Date
Name of the Investigator	Sign	Date
Name of the Impartial Witness	Sign	Date

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Annexure 16.13: Informed Assent Form Template

Instructions to Investigator:

1. The **Ethics Committee,** *Mahatma Gandhi. Medical College and Hospital, Jaipur* has developed the template in accordance with regulatory guidelines, to assist Investigator in the design of informed Assent document.
2. In order to make you understand the language and content of Informed Assent Document we have added guidance and examples. Please note guidance and examples are for your understanding and you need not include it in your Informed Assent Document which you intend to develop and share to participants in your study
3. In this template square brackets indicate where specific information is to be inserted. The explanation and examples are provided so as to enable you to properly write the Informed Assent Document.
4. Please note Informed Assent Document need to be administered for children of age group 7 to 18 Years and hence language used in Informed Assent Document should be as simple as possible.
5. For age group 7 to 18 Years you need to administer Informed Assent Document and ICD both.
6. Regarding requirements of audio-video consenting please refer to IEC SOP.

TEMPLATE ON FOLLOWING PAGE

Title of the Study:

1. Introduction:

Briefly state who you are and explain that you are inviting them to participate in the study you are doing.

(Example: We are doing study on disease, which is very common in this country. I am going to give you information and invite you to be part of this study. You do not have to decide today whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the study.)

There may be some words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask them to me.

2. Purpose of the Study

Explain in lay terms why you are doing the study. Use local and simplified terms for a disease, e.g., local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors

(Example: Malaria is one of the most common and dangerous diseases in this region. The study has been undertaken to know more about the disease)

3. Participant selection and voluntariness

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State why this participant has been chosen for this study. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.
(Example: We intend to enroll all children of age group --- to attend clinic to participate in the study) Indicate clearly that they can choose to participate or not. And child need not participate if don't want to.
(Example: Your participation in this study is as per your wish. You need not participate if don't want to. You may change your mind later and stop participating even if you agreed earlier.)

4. Procedures & Type of Study Intervention
Describe or explain the exact procedures that will be followed on a step-by-step basis in the first visit, We will also ask you a few questions about your general health and measure how tall you
are and how much you weigh. At the next visit, which will be two weeks later, you will again be asked some questions about your health ….
Include a statement about the time commitments of the study for the participant including both the duration of the study and follow-up (if relevant). In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the study will be finished.
(Example: The study takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____ (number of) days, for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.)

5. Side Effects
Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.
(Example: As already mentioned, this interview or procedure can have some unwanted effects. You may mention there are no side effects related to your participation in the study.)

6. Risks
Explain and describe any possible or anticipated risks. (Example: By participating in this study, it is possible that you will be at higher risk than you would otherwise be. OR there is no risk apart from what is encountered in routine care and procedure, or You may mention There are no side effects related to your participation in the study)

What if something goes wrong?
The sponsor has taken out insurance coverage in accordance with the legal requirements. During the study, any other medical treatment except for emergency situations must always be agreed beforehand with the study doctor. If personal injury is suspected to have occurred as a result of involvement in this

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study, your study doctor must be informed immediately so that he/she can inform the sponsoring company.

The insurance policy taken by sponsor covers any claim for medical care or compensation due to injury or death related to the study, wherein such medical care is required or injury or death has resulted from administration of any study drug or any other procedure carried out in accordance with the protocol for the study drug or any other procedure carried out in accordance with the protocol for the study or due to negligence of the sponsor.

In an event of an injury occurring to you because of your participation into this clinical trial, you shall be given free medical management as long as required or till such time it is established that the injury is unrelated to the trial, whichever is earlier.

You shall be entitled for financial compensation as per the orders of the Licensing Authority.

In case of death caused due to participation into this clinical trial, your nominee would be entitled for financial compensation as per the orders of the Licensing Authority.

7. Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. (Example: There may not be any direct benefit for you, but your participation is likely to help us find the answer to the study question.)

8. Confidentiality and who will review data and have access to data.

Study Doctor will replace your name with a special code that identifies you so that the data collected from your recorded is protected from unauthorized people. This code, along with your Study Information, will be used for the study purposes as mentioned above. Also, this code will not be linked to hospital records.

I would like to participate in the study:

Name of the Child	Sign	Date
Name of Parent/Guardian	Sign	Date
Relationship with the subject	Contact Details Parent/Guardian	
Name of Person conducting Assent Form	Sign	Date

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Phone : 0141-2770677, 2770798, 2771777, 2771001 – 3 Fax : 0141-2770677
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Part 2: Informed Consent Form

Participant's Initials: _____ Participant's Name: _____

Date of Birth / Age: _____

Please Initial Box

i. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

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

iii. I understand that the study investigator and study team, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand my identity will not be revealed in any information which may get published. [ ] [ ]

iv. I agree not to restrict the use of any data or results that arise from this study provide such a use is only for scientific purpose(s). [ ]

v. I agree to take part in the above study. [ ]

vi. I am aware that it has been agreed by the sponsor that in case of study related injury of Death, the *Sponsor* i.e., (*Name of Sponsor*), will provide complete *Medical Care as well as Compensation* for the Injury to the Individual and in case of death to his legal heirs. [ ]

Name of the parent	Sign/Thumb Impression	Date
Name of the LAR (Legally Acceptable Representative)	Sign/Thumb Impression	Date
Name of the Investigator	Sign	Date
Name of the Impartial Witness	Sign	Date

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Annexure 16.14: Informed Parent Consent Template

Principal Investigator:
Department of
Mahatma Gandhi Medical College and Hospital, Jaipur-302022.

1. Introduction:

Your child is invited to participate in this study/research project titled_____. Before you agree that your child participates in this study, you need to know the risks and benefits so that you can make an informed decision. This process is known as "informed consent".

This information sheet tells you about the research project for which your child is invited to participate. Please read the information carefully and discuss it with anyone you want. If you or your child have questions, please ask the Study Doctor or Study staff to answer them.

Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue. In case you decide to participate in the research project and then choose to step out at a later time, no new information will be collected post your withdrawal decision; however, any previously collected information will be utilized for the study analysis.

2. **Purpose of the Study:**

The purpose of this study is to_____

Briefly explain in lay language- the background of the problem, the need & purpose of the study, use simple self-explanatory language / words that can be understood by 7th Std student.

3. Participant selection:

We intend to enroll all children of age group --- (Brief eligibility criteria) to attend clinic to participate in the study)

4. Procedures & Type of Study Intervention:

The study will involve you answering a few questions about your child and going through your child's clinical and laboratory findings to collect information as per requirements of the study. There won't be any additional procedures required just for study purpose.

5. Duration of participation.

It includes time period from baseline visit (consenting visit) to first follow-up visit with the Institute.

6. Your responsibilities

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You need to answer few questions regarding your child's symptoms and allow us for clinical examination and to go through all the investigations done in the past or at the time of the current visit in order to collect information as per requirements of the study.

7. Side Effects

There are no side effects related to your child's participation in the study.

8. Risks

There will not be any additional risk other than those observed in routine care and procedure. Your child's treating doctor should have already explained about these to you.

What if something goes wrong?

The sponsor has taken out insurance coverage in accordance with the legal requirements. During the study, any other medical treatment except for emergency situations must always be agreed beforehand with the study doctor. If personal injury is suspected to have occurred as a result of involvement in this study, your study doctor must be informed immediately so that he/she can inform the sponsoring company.

The insurance policy taken by sponsor covers any claim for medical care or compensation due to injury or death related to the study, wherein such medical care is required or injury or death has resulted from administration of any study drug or any other procedure carried out in accordance with the protocol for the study drug or any other procedure carried out in accordance with the protocol for the study or due to negligence of the sponsor.

In an event of an injury occurring to you because of your participation into this clinical trial, you shall be given free medical management as long as required or till such time it is established that the injury is unrelated to the trial, whichever is earlier.

You shall be entitled for financial compensation as per the orders of the Licensing Authority.

In case of death caused due to participation into this clinical trial, your nominee would be entitled for financial compensation as per the orders of the Licensing Authority.

9. Benefits

There may not be any direct benefit for your child, but your child's participation is likely to help to generate reliable data.

10. Reimbursements

As all visits are as per routine care, no travel reimbursement will be given. There won't be any kind of reimbursement as study participant does not incur any additional cost by participating in the study.

11. Confidentiality and who will review data and have access to data.

While participating in this study, the Study Doctor will replace your child's name with a special code that identifies your child; however, as per the study requirement at least one name need to be entered (either first, middle or last name). This code, along with your child's Study Information, will be used for the study purposes as mentioned above. Also, this code will not be linked to hospital records.

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12. Alternatives to participating

This section is to be included only if the study involves administration of investigational drugs or new therapeutic procedures. It is important to explain and describe the established standard of care.

Example: If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the hospital.

13. Who to Contact

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact:

Name of PI: _____

This proposal has been reviewed and approved by Institutional Ethics Committee (IEC) which is a committee whose task is to make sure that study participants are protected from harm. If you wish to know more about the IEC, following are communication details.

Mailing Address IEC:
Ethics Committee
Mahatma Gandhi Medical College and Hospital,
Jaipur-302022. Email id: mgumst.ethics.committee@gmail.com
Chairperson of IEC: Professor (Dr.) S. C. Lodha
Ethics Committee, Mahatma Gandhi Medical College and
Hospital, Jaipur-302022.
Email id: mgumst.ethics.committee@gmail.com
Mobile: 9314618822
You will be given a copy of the Parent Information Sheet & signed Informed Consent Document.

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Part 2: Informed Consent Form

Participant's Initials: _____
Participant's Name: _____
Date of Birth / Age: _____

Please Initial Box

i. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

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

iii. I understand that the study investigator and study team, the Ethics Committee and the regulatory authorities will not need my permission to look at my child's health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand my child's identity will not be revealed in any information which may get published. [ ]

iv. I agree not to restrict the use of any data or results that arise from this study provide such a use is only for scientific purpose(s). [ ]

v. I agree to take part in the above study. [ ]

vi. I am aware that it has been agreed by the sponsor that in case of study related injury of Death, the *Sponsor* i.e., (*Name of Sponsor*), will provide complete *Medical Care as well as Compensation* for the Injury to the Individual and in case of death to his legal heirs. [ ]

----------	----------	----------
Name of the Parent/Guardian	Sign/Thumb Impression	Date
----------Name of the Investigator	---------- Sign	---------- Date
----------	----------	----------
Name of Impartial Witness	Sign	Date

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Annexure 16.15: Intimation of Start of Study

1. Project/Trial Code Number: _____
2. Title of the drug/multicentric trial: _____
   _____
   _____
3. Principal Investigator: _____
4. Clinical Study Site Address: _____
   _____
5. Sponsor: _____
6. Contract Research Organization (CRO) if any: _____
7. Date of sanction by EC, *IEC, MGMCH*, Jaipur 302022:
   _____
8. Date of start: _____

Date:

(Signature of Principal Investigator)

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Annexure 16.16: Annual/Periodic Review Report Form

IEC Code: _____
Protocol title:

_____

_____

Principal Investigator: _____
Is the study expected to extend beyond the projected duration: ☐ Yes ☐ No
If yes- provide reasons for not being able to complete the work in stipulated time: _____

_____

Are you applying for extension for the same: ☐ Yes ☐ No
If yes- period of extension requested? _____

Section B: Mandatory for Interventional Research

If the study pertains to retrospective case series / paraffin blocks / MRI or other radiological studies, etc. Please provide information on the status/progress of the study so far with regards to the final accrual/objective. Please mark what is not relevant as not applicable.

1) a) Have any SAEs been noted since the last status report? ☐ Yes ☐ No ☐ NA

If 'Yes', attach in format below

S. R. no	SAE Event	Date of occurrence	Report type	IEC notification date	At site\ other site

b) In case of multicenter trials state whether reports of offsite SAEs have been submitted to the IEC
☐ Yes ☐ No ☐ NA

2) Have any Deviations/Violations been noted since the last status report?
☐ Yes ☐ No ☐ NA

If 'Yes', attach in format below

Deviation description	Date of deviation	IEC notification	Is patient safety affected, if yes, explain measures to taken to address safety

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3) Have any unanticipated problems involving risks to participants or others (including but not limited to adverse events) been noted?
☐Yes ☐ No ☐ NA
If Yes please provide a summary-
Patient No.-
Adverse Event Description-
Severity-
Start Date-End Date-
Relatednes-
Outcome-
Action Taken- If Yes, Specify Details as mentioned below:

S. R.	Medication	Dose	Frequency	Route	Start Date	Stop Date /Ongoing
1						

4) Have there been any amendments in any study documents?
☐ Yes ☐ No
If 'YES', please provide in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval

5) Have any Informed Consent documents been amended since the last status report?
☐Yes ☐No ☐ NA
If 'YES', fill in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval	Did Ongoing Patients consented

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6) Have any participating investigators been added or deleted since the last status report was submitted to IEC?

☐Yes ☐ No

(If 'YES', should it be Notify to EC) ☐Yes ☐No

7) Has there been any presentation/publication related to the data generated in this trial?

☐Yes ☐ No

(If, 'YES', kindly attach a publication copy)

SIGNATURES: _____

Principal Investigator:_____

Date: _____

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Annexure16.17: Waiver of Consent Request Form

Application form for requesting waiver of consent

Principal Investigator's name: .....

Study Title: .....

.....

Please specify reason(s) for requesting waiver. (You may tick option(S))

1. Research involves 'not more than minimal risk'
2. There is no direct contact between the researcher and participant
3. Emergency situations as described in ICMR Guidelines
4. Any other (please specify) .....

Also confirm if protocol mentions following statements (Kindly tick)

1. Statement assuring that the rights of the participants is not violated
2. State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant.

Principal Investigator's signature with date: .....

IEC decision at full board meeting dated....., Waiver granted: Yes / No

If not granted, reasons .....

.....

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Annexure 16.18: Study Completion Report Form by PI

IEC Code. –
Study Title: -
PI name: -

Sponsor -

Duration of the study -

Study Start Date –
Completion Date -

Summary of Protocol participants:
Study Participants

- Screened: _____
- Screen failures: _____
- Enrolled: _____
- Withdrawn Subject: _____
- Ongoing Subjects: _____
- Completed treatment: _____
- Patients lost to follow up: _____
- Vulnerable patients enrolled
  YES \ NO
  If yes, please specify:

Results (brief) (use extra blank sheets, if more space is required)-
a) * 250-300 words, with aims, methods, results, discussion and conclusion as in an abstract
b) Summary and Conclusions
c) Details of new leads/information obtained, if any:
*Note: In case of Pharma sponsored projects, if the final report is not available from sponsor, it may be submitted later to the IEC once it is ready.

Conclusion *

Presentation/publication related to the data generated in this trial
If yes: please enclose reprint of research publication

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Serious Adverse Events at our centre (Total number and type) Note: applicable for Interventional study
Whether all Serious Adverse Events were intimated to the IEC (Yes/No)
Protocol deviations/violations (Type and Number) Whether all Protocol deviations/violations were intimated to the IEC (Yes/No)
Signature of PI
Date:
***Mandatory fields**

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Annexure 16.19: Essential Elements of Undertaking by Investigator

(Based on *New Drugs and Clinical Trials Rules, 2019*)

A copy of the undertaking by the Principal Investigator must be submitted along with the submission package. The undertaking by the Principal Investigator must have the following elements:

- Full name, designation, Department, complete address of the Principal Investigator
- Name and address of the site or other facility where the clinical trial will be conducted
- Education, training & experience of the Principal Investigator for the clinical trial [Attach details including Medical Council /Dental Council registration number, and / or any other statement(s) of qualification(s)]
- Name and address of all clinical laboratory facilities or Central Laboratory to be used in the study
- Name and address of the Ethics Committee
- Names of the other members of the research team (Co - Investigators) who will be assisting the Investigator in the conduct of the investigation (s)
- Protocol Title and Study number of the clinical trial to be conducted by the Investigator
- Commitments:

o I have reviewed the clinical trial protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
o I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
o I agree to personally conduct and/or supervise the clinical trial at my site.
o I agree to inform all Subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.

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- I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.
- I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- I agree to promptly report to my Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- I agree to inform all unexpected serious adverse events to the Sponsor as well as to my Institutional Ethics Committee within 24 hours of the notification by the study subject.
- I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.
- I shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Sponsor and Ethics Committee that accorded approval to the study protocol within 24 hours of their occurrence.
- I agree to provide information to clinical trial subject through Informed Consent Process as provided in Appendix V about the essential elements of the clinical trial and the subject's rights to claim compensation in case of trial related injuries & death. I will also inform the subject or his/ her legal heirs of their rights to contact the sponsor/ Clinical Research Organization/ local representative in case of foreign sponsor of the trial and Ethics Committee for the purpose of making claims in the case of trial injury or death.

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- In case of clinical trial related injury, I shall request the Ethics Committee to review and make recommendations for the payment for medical treatment as well as compensation for the trial related injury or death of the subject.

Signature of Investigator with date

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Annexure 16.20: Risk Benefit Assessment Tool

HIGH RISK/LOW BENEFIT (CLASS-A)	HIGH RISK/HIGH BENEFIT (CLASS-B)
Risks: • Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. Of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures	**Risks:** • Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. Of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures
Benefits: • Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	**Benefits:** • Completely new cure • Preventive for life i.e., Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects vis a vis existing treatment • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pill vs Surgery) • Extension of benefits / availability of treatment post trial • Benefits large no. of participants

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LOW RISK/LOW BENEFIT (CLASS-D)	LOW RISK/HIGH BENEFIT (CLASS-C)
Risks: • Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation a variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations • Standard operating / surgical procedures	**Risks:** • Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation a variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations **Standard operating / surgical procedures**
Benefits: • Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	**Benefits:** • Completely new cure • Preventive for life i.e., Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects vis a vis existing treatment • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pill vs. surgery) • Extension of benefits / availability of treatment post trial • Benefits large no. of patients

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Annexure 16.21: Study Assessment Form

IEC Code No: _____ Review Date: _____
Principal Investigator: Initial / Resubmission
Study Title: ----------

Note: Reviewer may tick the appropriate box and may mention comments if any

1. Conflict of interest of IEC Member

Yes ☐ No ☐

2. Objectives of the study:

Clear ☐ Unclear ☐ NA ☐

3. Need for Human Participants

Yes ☐ No ☐ NA ☐

4. Methodology and Eligibility Criteria:

Appropriate ☐ Inappropriate ☐ NA ☐

5. Justification for Vulnerable Population/Special Group Population

Appropriate ☐ Inappropriate ☐ NA ☐

6. Risks and Benefits Assessment

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Acceptable ☐ Unacceptable ☐ NA ☐

---

7. Control Arms (Placebo), If any:

Yes ☐ No ☐ NA ☐

---

8. Contents and Language of Consent: Appropriate / Inappropriate

Appropriate ☐ Inappropriate ☐ NA ☐

---

9. Provision for Insurance, compensation for participation and study related injury

Appropriate ☐ Inappropriate ☐ NA ☐

---

10. Treatment for study related Injury:

Appropriate ☐ Inappropriate ☐ NA ☐

Additional Comments:

Reviewer's Name: _____
Reviewer's Signature: _____
Date: _____

Signatory of SOP approval
Member Secretary, ethics committee

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Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

Institutional Ethics Committee
Mahatma Gandhi University of Medical Sciences & Technology
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

Annexure 16.22: EC Approval Format

Date: Ref. No.:

To

Dr. < Name Principal Investigator>,
Department of
Mahatma Gandhi Medical College and Hospital,
Jaipur-302022. Rajasthan, India

Protocol Number: _____

"Title of Protocol": _____

Reference: **Your EC submission letter dated**

Sub: EC approval of study documents to conduct the referenced clinical trial

Dear**< Name Principal Investigator/Sub-Investigator>,**

With reference to submission letter ref. no._____ dated _____, we write to inform you that the ethics committee in its meeting held on <date> at <time> in the premises of *Mahatma Gandhi Medical College and Hospital, Jaipur* reviewed and discussed your proposal for conducting the clinical study at *Mahatma Gandhi. Medical College and Hospital, Jaipur-302022.*

The Ethics Committee has conducted a scientific and ethical review of the study and hereby grants you permission to conduct the clinical study in its presented form. This approval is valid for the entire period of the study.

The Ethics Committee reviewed the following documents and is agreeable to conducting the study complying with these documents:

1.
2.
3.
4.

Signatory of SOP approval
Member Secretary, ethics committee

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Member Secretary
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The following members attended the ethics committee meeting for the review of this clinical study protocol. This satisfies the quorum necessary for such meetings.

S. No.	Name (with Qualifications)	Designation	Affiliation
1	**Dr. S. C. Ladha**, 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**
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**

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Member Secretary, ethics committee

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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

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/ decision making procedures of the committee and not even present at the time of voting/decision making procedures.

Please note that you are required to follow the requirement given below for this study:

- Do not implement any deviation from or change to the protocol approved by this ethics committee without the prior written approval of this ethics committee.
- Deviation / changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to the subjects or when changes involve only logistical or administrative aspects of the trial (e.g., change of study monitor(s), telephone number(s)).

Promptly report the following to the Ethics Committee:

- Any changes to or deviation to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial subjects.
- Any changes in the approved Informed Consent Form.
- All Serious Adverse Events (SAE).
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the following reports to the Ethics Committee:

- Annual report about the progress of the study.
- A copy of final study report.

The ethics committee is organized and operates according to the requirements of *New Drugs and Clinical Trials Rules, 2019, Central Drugs Standard Controller Organization (CDSCO), Drugs*

Signatory of SOP approval
Member Secretary, ethics committee

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Controller General of India (DCGI), Indian Council of Medical Research (ICMR) and International Conference on Harmonization-Good Clinical Practices (ICH-GCP).

Yours sincerely,

Professor (Dr) S. C. Lodha
Chairperson, Ethics Committee
Date: ------/-----/----------
(DD/MM/YYYY)

Professor (Dr.) R. K. Sureka
Member Secretary, Ethics Committee
Date: ------/-----/----------
(DD/MM/YYYY)

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Member Secretary, ethics committee

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Annexure 16.23: Expedited review application

IEC Code: _____
1. Principal Investigator's Name: _____
2. Title of Project: _____

3.Names of study team members:
_____
_____

4.Brief description of the project:
_____
_____

5. State reasons why expedited review from IEC is requested? (Tick applicable)
Risks to subjects is more than minimal
Risks to subjects are minimal
Research involving materials (data, documents, records, or specimens) that have been collected, for non-research (clinical) purposes

Are children included in the study? Yes No

Does the research involve vulnerable population? Yes No

Any other reasons: _____
Principal Investigator's signature: _____ **Date** _____
Recommendations by the IEC Member Secretary:
Consider for expedited review

Cannot be consider for expedited review, Reasons _____
_____

Signature of the Member Secretary: _____
Date-_____

Final Decision: ☐ ☐ Expedited Review ☐ ☐ For Full Board Meeting

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Member Secretary, ethics committee

Member Secretary
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Annexure: 16.24: Considerations for Genetic Research

Investigator:
IEC Code:
Study Title: _____

1. The samples must be made anonymous to maintain confidentiality.
2. The investigator must establish clear guidelines for disclosure of information, including interim or inconclusive research result.
3. The appropriateness of the various strategies for recruiting participants and their family members must be considered.
4. Are there family members involved in research?
5. Family members must not be implicated in the studies without consent.
6. The samples destruction procedure
7. Genetic counseling should be offered.
8. Genetic Consenting if available.

Comments: _____

Primary Reviewer: _____ Date: _____

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Annexure 16.25: Review Exemption Application Form

IEC Code: _____
1. Principal Investigator's Name: _____
2.Title of Project: _____
_____
3. Names of study team members
_____
_____
4. Brief description of the project:
_____
_____
_____

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project.
Please check that your application / summary include:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

6. State reasons why exemption from IEC review is requested? (Tick applicable)

☐ Audit of educational practices ☐
☐ Analysis of data freely available in the public domain ☐
☐ Any other (please specify)---------- ☐

Principal Investigator's signature: _____ **Date** _____

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Annexure 16.26: Serious Adverse Event (SEA) Report Assessment Form

SERIOUS ADVERSE EVENT REPORT		IEC Code- Regulated by DCGI: Yes / No CTRI Reg. No:	
1	Title of project:		
2	Principal Investigator:		
3	Report Date: Report Type: ☐ Initial ☐ Follow-up _____ If Follow-up report, State Date of Initial report_____ ☐ Final If Final report, State Dates of Initial/Follow up report		
4	Date of Occurrence of SAE:		
5	Subject Case No: Subject Trial ID:	5a. Age: 5b. Gender: ☐ Male ☐ Female	
6	State SAE Event term:		
7	SAE Relatedness and causality assessment justification:		
8	The cost of treatment/hospitalization was borne by, ☐Patient ☐Institute ☐Sponsor/CRO		
Drug information (refers to drug/ device/ procedure under investigation)			
9	IP/ Placebo (include generic name)/device/intervention:		
10	Dose: Dosage Form:	11	Route(s) of administration:
12	Therapy Dates (From/To):	13	Therapy duration:
Was study intervention discontinued due to event? ☐ ☐ Yes ☐ ☐ No			
14	Did the reaction decline after stopping the drug/procedure (De-challenge & Rechallenge information) ☐Yes ☐No ☐NA		
Concomitant drugs and history (drugs that the patient maybe on)			
15	Concomitant drug(s) and date of administration		

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16	Patient relevant history (e.g., diagnosis, allergies): (Tick in the applicable box) (This is applicable only for regulated clinical trials) R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under: a) 0.5 Terminally ill patient (expected survival not more than (NMT) 6 months) ☐ ☐ b) 1.0 Patient with high risk (expected survival between 6 to 24 months) ☐ c) 2.0 Patient with moderate risk ☐ d) 3.0 Patient with mild risk ☐ e) 4.0 Healthy Volunteers or subject of no risk ☐

SAE Details

17	**Description of serious adverse event** (indicate if this is follow-up report and if so, include follow-up information only)			
18	Describe the medical treatment provided (if any) to the research subject: This is an update on treatment given during hospitalization and /or used for management of the SAE.			
	Medication	**Dose**	**Start Date**	**End Date**
19	Outcome was ☐ Resolved ☐ Ongoing ☐ Death			
20	Was the research subject continued on the research protocol? ☐ Yes ☐ No ☐ NA (Mark 'NA' in case of death)			
21	In your opinion, does this report require any alteration in trial protocol? Yes No If yes, then please specify. _____ Name of Principal investigator: _____ Profession (Specialty): _____ Signature of Principal investigator _____ Date: _____ Contact No. of PI: _____ Upon receipt of this report, the IEC/MGMCH will decide whether additional information is needed or whether further investigation of the incident is required. A follow-up report with further details should be submitted by PI within 10 days or earlier (of occurrence of the SAE) to the IEC.			
For IEC use only				

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Member Secretary
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Final Assessment of IEC		
Response of IEC at meeting held on:		
Changes to the protocol recommended?	Yes	No
If Yes , Specify ----------		
Changes to the informed consent form recommended?	Yes	No
If Yes , Specify ----------		
Terminate Project		
Request for additional information ----------		
Till additional information is received trial will be	Continued	Suspended

IEC Chairperson / Member Secretary Sign & date

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Annexure 16.27: Request or Complaint Record Form

Received by: Date Received:	
Request from: ☐ Participant ☐ CRO ☐ Sponsor ☐ Government ☐ Any other Please Specify: _____	**Mode of request** ☐ Telephone call No..... ☐ Fax No ..... ☐ Letter/Date ..... ☐ E-mail / Date..... ☐ Walk-in/ Date / Time..... ☐ Other, specify .....
Requester's Name:	
Contact Address: Phone:	
Title of the Study:	
Starting date of participation (if request by participants):	
Request:	
Action taken:	
Outcome:	

Name of the Chairperson/ IEC Secretariat: _____
Signature of the Chairperson/ IEC Secretariat: _____ Date: _____

Signatory of SOP approval
Member Secretary, ethics committee

6.5

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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Annexure 16.28: Premature Termination / Suspension / Discontinuation Report

IEC Code: _____
Protocol Title: _____

_____

PI: _____
Sponsor: _____
IEC Approval Date: _____

Please tick the appropriate
- Premature Termination
- Suspension
- Discontinuation

Reason for Termination/Suspension/Discontinuation:

_____

Study Start Date: _____	Termination / Suspension / Discontinuation Date:

Study Participants
- Screened: _____
- Screen failures: _____
- Enrolled: _____
- Withdrawn Subject: _____
- Ongoing Subjects: _____
- Completed treatment: _____
- Patients lost to follow up: _____
- Vulnerable patients enrolled: YES \ NO

If yes, please specify:

Type of SAEs (Total Nos.):
Have any adverse events or outcomes reported to the IEC:

Have there been participant complaints or feedback about the study
Yes /No If yes Describe

Summary of Results (if any) :

PI Signature:	Date:

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Annexure 16.29: Deviation / Non-Compliance/ Violation Reporting Form

INSTRUCTIONS:
Please report single event in one reporting form
Specify if Deviation (D)/Violation (V)
Date of Occurrence: _____
Study status: _____
D/V identified by- ☐ ☐ Principal Investigator / study team
☐ Sponsor / Monitor
☐ IEC
Complete Details of D/V: _____
_____
Action taken by PI/Co-PI/Co-I: _____
_____ Impact on Trial participant (if any): _____ Are any changes to the project/protocol required?
☐ Yes ☐ ☐ ☐ No ☐
Name of PI: _____
Sign of PI: _____
Date: _____
IEC Secretariat Comments: _____
_____
_____

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Annexure 16.30: Reminder Letter to Investigator

Name of Principal Investigator: _____
Ref: - Project Title:

_____

_____

The above referenced project was approved by the IEC on Date_____ and is due for continuing annual review by the IEC.
Kindly submit the annual study report /Periodic Review report application on or before_____.
In case the projects, have been completed / terminated, kindly complete the appropriate forms and submit to
IEC on or before _____
Thanking you for your co-operation,
Yours truly,

Signature with date
Member Secretary/ Admin Manager/ IEC Co-coordinator

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Annexure 16.31: Site Monitoring Visit Report Form

1)	IEC Code:
2)	Title:
3)	Principal Investigator:
4)	Date of IEC approval:
5)	Start Date of study:
6)	Duration of study:
7)	Date of monitoring visit:
8)	Reason for monitoring: ☐ Routine ☐ For Cause (State reason) ☐ Protocol Violations/Deviations ☐ SAE reporting ☐ Recruitment rate ☐ Other
9)	Last Monitoring done: ☐ Yes Date of last monitoring _____ ☐ No
10)	Project Status: ☐ Ongoing ☐ Accrual Completed ☐ Follow-up ☐ Completed ☐ Suspended ☐ Terminated ☐ Closed ☐ Closed Prematurely In case of the response to the question Suspected, Terminated or Closed Prematurely is ticked, Kindly provide reason _____

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
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MGMC, Jaipur

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11)	Recruitment Status: ➢Total participants to be recruited: _____ ➢Screened: _____ ➢Screen failures: _____ ➢Enrolled: _____ ➢Withdrawn: _____ Reason: _____ ➢Discontinued: _____ Reason: _____ ➢Completed: _____ ➢Ongoing: _____
12)	Protocol a) Have there been any amendments to the Protocol? ☐ Yes ☐ No
	If Yes then state changes leading to amendment: _____
13)	Informed Consent a) Is Informed consent obtained from all enrolled participants? ☐ Yes ☐ No b) Have there been any amendments to the ICF? Yes No If Yes then state changes leading to amendment: _____ _____ c) Is the Informed consent form version approved by IEC? ☐ Yes ☐ No d) Is the latest version of the ICF being used for the study? ☐ Yes ☐ No If No, Specify Reasons .....
14)	Any Protocol Deviations/Violations noted? ☐ Yes ☐ No ☐ NA Have all the deviations/violations notified to IEC? ☐ Yes ☐ No Comments (If Any)
15)	Has the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No

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16)	Are all the Case report forms complete? ☐ Yes ☐ No ☐ NA Has there been any AE/SAE on the study? ☐ Yes ☐ No ☐ NA If Yes a) No. of Adverse events: _____ b) No. of Serious adverse events: _____ c) No. of deaths reported: _____ ➢ Deaths unrelated to participation in the trial: _____ ➢ Deaths possibly related to participation in the trial: _____ ➢ Deaths related to participation in the trial: _____ Comments (If Any)
17)	Are Study documents secured and confidentiality maintained: ☐ Yes ☐ No
18)	Are the Investigational drugs accountability and prescription procedures performed and documented? ☐ Yes ☐ No ☐ NA If 'Yes' kindly state the issues: _____
19)	Any are there any changes to the study personnel? ☐ Yes ☐ No ☐ NA If 'Yes' kindly state the same: _____ Is the change notified to IEC? ☐ Yes ☐ No ☐ NA
20)	No. of participants monitored during this visit: _____
21)	Duration of the visit: _____
22)	Any outstanding tasks/action items from the visit?

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Monitoring visit conducted by:
Signature and Date _____
Name of study team member present: _____
Signature and Date: _____

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Annexure 16.32: EC Secretariat Duty Delegation Log

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

Name and Signature of Site Personnel	Short signature	Designation	Responsibility (Refer below table)	Start date with short sign and date		End date with short sign and date	
Name:		Chairperson	1 to 8		*Shorts ign:*		*Short sig*
Signature:					*Date:*		*Date:*
Name:		Member Secretary	9 to 28		*Short sign:*		*Short sig*
Signature :					*Date:*		*Date:*
Name:		Administrative Worker	29 to 35		*Short sign:*		*Short sig*
Signature:					*Date:*		*Date:*
Name:		Helper	36-41		Short sign:		Short sig
Signature:					*Date:*		*Date:*

I hear by confirm that the information furnished above is correct to the best of my knowledge.
The Principal and Controller
Mahatma Gandhi Medical College and Hospital,
Jaipur-302022. Rajasthan. India.
Full name Signature Date:

1) Conduct EC meetings and be accountable for independent and efficient functioning of the committee
2) Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
3) Ratify minutes of the previous meetings

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Member Secretary, ethics committee

Member Secretary
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4) In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
5) Seek COI declaration from members and ensure quorum and fair decision making.
6) Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
7) Chairperson is responsible to chair the meetings and liaise directly with the Director/Officer-in Charge of the Institute, report the meeting outcomes to the Director, invite independent consultants to provide special expertise to the EC on proposed research protocol if required.
8) Chairperson should work in close co-ordination with the Member Secretary and review along with the member secretary all the minutes, proposals and work towards the smooth function of the EC.
9) Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
10) Schedule EC meetings, prepare the agenda and minutes
11) Organize EC documentation, communication and archiving
12) Ensure training of EC secretariat and EC members
13) Ensure SOPs are updated as and when required
14) Ensure adherence of EC functioning to the SOPs
15) Prepare for and respond to audits and inspections
16) Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
17) Assess the need for expedited review/ exemption from review or full review.
18) Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
19) Ensure quorum during the meeting and record discussions and decisions.
20) Organizing an effective and efficient tracking procedure for each proposal received
21) Preparation, maintenance and distribution of study files
22) Allocation of project reviews to specific members to facilitate efficient dispensation of the projects.
23) Organizing IEC meetings regularly
24) Receive and check for the completeness of the documents for review by the EC.
25) Communicating with the IEC members and investigator applicants
26) Organizing the preparation, review, revision and distribution of SOPs

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27) Work in unison with the EC members and the investigators to reduce the turn-around time of the study proposals sent to the EC for review.
28) Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.
29) Correspondence with the IEC members and external experts
30) Correspondence with the investigators
31) Pre and post arrangements of IEC meetings
32) Preparing agenda and minutes of the IEC meetings
33) Answering queries of the investigators
34) Filing study related documents
35) Archiving and maintaining the study files
36) Assisting the secretariat in arranging the IEC meetings
37) Dispatching sets of study documents to IEC members and external experts
38) Receiving the study related documents from and dispatching the IEC letters to the investigators
39) Filing study related documents
40) Archiving and maintaining the study files
41) Correspondence with the IEC members and external experts

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Annexure 16.33: Self-Assessment of IEC Members

FORM A
For Assessment of overall IEC performance
Document Available: Yes/No.

Section	Assessment Elements	Yes/No	Comments Regarding Compliance
Section A	**Authority for formation of IEC and Induction Procedure**		
1	Authority for formation of Ethics Committee and Induction of IEC Members		
2	Was the IEC Chairperson, Member Secretary, Secretariat appointed by high-ranking authority of the Institute?		
3	Was the induction procedure conducted as per the IEC SOP?		
Section B	**Training of IEC Members**		
4	Were the members trained at least annually regarding CDSCO, DCGI NDCT Rules, 2019, ICMR Guidelines ICH-GCP, IEC & Site SOP?		
5	Does IEC office have required training records for all Members filed under Individual Members Records		
Section C	**Periodic Study Documents Review**		
6	Does the IEC request Annual Report from the investigator?		
7	Are study annual reports being reviewed by the IEC regularly?		
Section D	**Protocol Review**		
8	Do the IEC members receive protocol and other study related documents (initial dossier) at a specified time prior to IEC meeting?		
9	Does the IEC review the investigators qualification and experience in clinical trials to conduct the study?		

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10	Does the IEC review adequacy of study team including the supporting staff, facilities available or management in case of emergencies arising from the research project?		
11	Does IEC evaluate the appropriateness of study design with respect to objectives of the study, methodology, risks involved to the human subjects while participating in the research project?		
12	Does the IEC identify the anticipated risk to the human subject and whether these risk have been minimized?		
13	Does the IEC assess risk benefit?		
14	Does the IEC follow IEC SOP on conditions for expedited meetings?		
15	Does the IEC follow IEC SOP regarding how the decisions for approval or disapproval for the study are made?		
16	Does the IEC follow IEC SOP for communicating the study decision to the investigator?		
17	Does the IEC follow IEC SOP for continuous review of the studies?		
18	Does the IEC ensure that the human participant is not subjected to unnecessary risky intervention during the study participation?		
19	Does the IEC consider whether the study sponsor has adequate insurance to cover treatment of injury related to the study?		
Section E	**ICF Review**		
20	Does IEC have an informed consent template to guide the investigators in writing the ICF?		

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21	Does IEC supervise Informed consent processor, is the process reviewed?		
22	Does the IEC follow IEC SOP that lists conditions requiring wavier of ICF?		
Section F	**Deviation/Non-compliance/Violation**		
23	Does IEC take required action against the investigator in case of violation, deviation, noncompliance or in condition where patient safety has been compromised?		
Section G	**Review of Serious Adverse Events**		
24	Does IEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation Calculation and reporting to the licensing authority within the stipulated time?		
25	Does IEC check whether compensation is paid to patient and whether amount is verified by IEC?		
26	Does IEC verify whether adequate medical care is provided for serious adverse events as per applicable rules and regulations?		
Section H	**Section H Site Monitoring**		
27	Does the IEC follow IEC SOP to review all adverse events of the research project?		
28	Does the IEC ensure that the ICF is in a simple language and understood well by the patient?		
29	Does the IEC reviews possibilities of any financial or other incentives offered to the participants for their study participation?		
30	Document listing all the rights and responsibilities of the subject in a charter.		

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31	Does the IEC review the data collected to ensure patient safety?		
32	Does IEC regularly monitor the site as per IEC SOP, and are monitoring reports discussed in Full Board Meeting?		
Section I	**Agenda, Minutes, Conduct of Meeting**		
33	Are the timelines for IEC meeting and expedited meetings being followed as per IEC SOP?		
34	Does the IEC consider whether the quorum has been met during the full board meeting?		
35	Does Minutes cover all require deliberations?		
36	Does chairman reassess the quorum when any member withdraws from the decision making and is recorded in the minutes?		
Section J	**Confidentiality / Conflict of interest agreement**		
	Does the IEC follow IEC SOP for Confidentiality disclosure and, is there a provision to address potential conflict of interest of IEC members?		
Section K	**Maintenance of active study files**		
	Are the IEC documents being properly maintained and stored as per the IEC SOP?		
Section L	**Complaints**		
	Does the IEC have provision whereby enrolled human subjects can file complaints and address their grievance regarding their study participation?		

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Section M	**Policy Financial declaration of payments received and disbursed**		
	Does the IEC reviews justification for including vulnerable patients in the study?		
Section O	**Overall Assessment**		
	The ethics committee should do a root cause analysis to identify if there is a process failure or a system failure		
	Does the Ethics committee assign responsibilities to the members with the objective to involve every member in decision making process?		

Assessment Performed by:

Signature and Date of Assessor:

FORM B

Performance of Chairperson/ Member Secretary /Secretariat

Mention individual (tick) who is performing the evaluation

- ☐ IEC Chairman
- ☐ IEC Member Secretary

Name of individual who is conducting self-performance: ..... Total number of meetings attended annually ..... Out of .....

Number of protocol review (initial)	
Pharma Sponsored	
Investigator Initiated	
Others	
Number of SAE reviewed	
Number of annual study reports reviewed	
Preparedness of meeting	
Periodic Reviews Conducted.	

Evaluation regarding regulatory training:

Overall performance is poor/ fair/ average/ good/ excellent

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Areas of improvement required: _____

Signature of Assessor: _____

Name of Assessor: _____

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Annexure 16.34: Document Request Form for Inactive Files

Principal Investigator:		
Sponsor:		
Title of the study		
Protocol No.:	IEC Code:	IEC Approval Date:

Name of Document requested: _____
Document Date and Version (If applicable): _____
Requested by: _____
Sign & Date of Requester: _____
Sign & date of IEC Member Secretary or Chairperson: _____

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Annexure 16.35: IEC Meeting Attendance Log

Protocol: Title: _____

_____

Date of Meeting: _____

Time of Meeting: _____

Location of Meeting: _____

_____

S. No.	Name	Role in EC	Opinion for approval (Yes / No)	Attendance (Signature)
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				

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Annexure 16.36: Rights and Responsibilities of Research Patient (English & Hindi)

Rights of Research Participant

- Right to voluntary participation in research study.
- Right to know about Institutional Ethics Committee and its responsibilities towards protecting patients' rights, safety and well-being involved in a research project and to provide public assurance of that protection
- Right to information about Research Study in an understandable language.
- Right to informed consent and if necessary, audio-video consenting before participation in any Research Study.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to receive quality healthcare in a safe, clean environment without discrimination because of race, age, color, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgmental and non-threatening manner.
- Right to information regarding investigational product, duration of study, treatment option available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation in an understandable language.
- Right to be informed of the risks, benefits and alternatives of proposed treatment
- Right to privacy and confidentiality.
- Right to be informed on how to voice a complaint to express concerns, violation of your rights and/or grievance and seek redressal
- Right to participation in research and innovative therapies.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records
- Right to get 24 hours emergency contact details of Research doctor
- Right to get contact details of Chairperson and Member Secretary of Institutional Ethics Committee.

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अनुसंधान प्रतिभागी के अधिकार।

- शोध अध्ययन में स्वैच्छिक भागीदारी का अधिकार।
- संस्थागत आचार समिति के बारे में जानने का अधिकार और एक शोध परियोजना में शामिल मरीजों के अधिकारों, सुरक्षा और कल्याण की रक्षा के प्रति उनकी जिम्मेदारियों और उस सुरक्षा का सार्वजनिक आश्वासन प्रदान करना
- शोध अध्ययन के बारे में समझने योग्य भाषा में सूचना का अधिकार।
- सूचित सहमति का अधिकार और यदि आवश्यक हो, तो किसी भी शोध अध्ययन में भाग लेने से पहले ऑडियो-वीडियो सहमति।
- बिना कोई कारण बताए अध्ययन में किसी भी समय भाग लेने से इंकार करने या भाग लेने से इंकार करने का अधिकार।
- नस्ल, उम्र, रंग, धर्म, राष्ट्रीयता, संस्कृति, जातीयता, भाषा, विकलांगता, लिंग या भुगतान के तरीके के भेदभाव के बिना एक सुरक्षित, स्वच्छ वातावरण में गुणवत्तापूर्ण स्वास्थ्य सेवा प्राप्त करने का अधिकार।
- गैर-निर्णयात्मक और गैर-खतरनाक तरीके से गरिमा, सम्मान और शिष्टाचार के साथ व्यवहार करने का अधिकार।
- जांच उत्पाद, अध्ययन की अवधि, देखभाल के मानक के अनुसार उपलब्ध उपचार विकल्प, प्रत्याशित व्यय, किसी भी चोट के चिकित्सा प्रबंधन की जानकारी और किसी भी अध्ययन से संबंधित चोट या मृत्यु के मामले में मुआवजे या किसी समझने योग्य में भागीदारी के लिए प्रदान किए गए मुआवजे के बारे में जानकारी का अधिकार भाषा: हिन्दी।
- प्रस्तावित उपचार के जोखिमों, लाभों और विकल्पों के बारे में सूचित होने का अधिकार * गोपनीयता और गोपनीयता का अधिकार।
- चिंता व्यक्त करने, अपने अधिकारों का उल्लंघन और/या शिकायत करने और निवारण की मांग करने के लिए शिकायत कैसे करें, इस बारे में सूचित होने का अधिकार
- अनुसंधान और नवोन्मेषी उपचारों में भागीदारी का अधिकार।
- नैदानिक और चिकित्सीय प्रक्रियाओं के लिए सहमति का अधिकार। नैदानिक अभिलेखों तक पहुँचने का अधिकार
- अनुसंधान चिकित्सक के 24 घंटे आपातकालीन संपर्क विवरण प्राप्त करने का अधिकार संस्थागत आचार समिति के अध्यक्ष और सदस्य सचिव के संपर्क विवरण प्राप्त करने का अधिकार।

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Responsibilities of Research Participant:

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (if available)
- To be compliant with research protocol and procedures
- To ask question when he/she does not understand what the doctors, research study team, or other healthcare team members tells about diagnosis or treatment
- To inform your research study doctor and research study team, immediately in case of any injury or development of any new medical conditions
- Not to take any medications without the knowledge of research doctor and research study team
- To disclose to doctors and research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year
- Provide complete and accurate information about your health including your previous medical history, and all the medications that you are presently taking including alternative treatments like Ayurveda, Homoeopathy, Unani or herbal medications, all records of previous investigations and treatment and of allergic reactions, especially sensitivity to any drug
- To follow instructions, advice and restrictions regarding treatment plan and visit schedules
- To treat hospital staff and study team with courtesy

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- पूरा नाम, आयु, पता, टेलीफोन सहित सही और पूर्ण जनसांख्यिकीय जानकारी प्रदान करने के लिए नंबर और ई-मेल आईडी (यदि उपलब्ध हो)|
- अनुसंधान प्रोटोकॉल और प्रक्रियाओं का अनुपालन करने के लिए|
- प्रश्न पूछने के लिए जब वह समझ नहीं पाता है कि डॉक्टर, शोध अध्ययन दल, या अन्य|
- स्वास्थ्य देखभाल टीम के सदस्य निदान या उपचार के बारे में बताते हैं अपने शोध अध्ययन चिकित्सक और शोध अध्ययन दल को किसी भी चोट के मामले में तुरंत सूचित करने के लिए या
- किसी भी नई चिकित्सा स्थिति का विकास अनुसंधान चिकित्सक और शोध अध्ययन दल की जानकारी के बिना कोई दवा नहीं लेना
- डॉक्टरों और शोध अध्ययन दल को खुलासा करने के लिए यदि वर्तमान में किसी अन्य नैदानिक परीक्षण का हिस्सा है या था
- पिछले एक वर्ष में किसी अन्य नैदानिक परीक्षण में भाग लिया हो अपने पिछले चिकित्सा इतिहास सहित अपने स्वास्थ्य के बारे में पूर्ण और सटीक जानकारी प्रदान करें,
- और वे सभी दवाएं जो आप वर्तमान में ले रहे है जिनमें वैकल्पिक उपचार जैसे आयुर्वेद, होम्योपैथी, यूनानी या हर्बल दवाएं, पिछली जांच और उपचार के सभी रिकॉर्ड शामिल हैं।
- एलर्जी प्रतिक्रियाएं, विशेष रूप से किसी भी दवा के प्रति संवेदनशीलता उपचार योजना और यात्रा कार्यक्रम के संबंध में निर्देशों, सलाह और प्रतिबंधों का पालन करने के लिए
- अस्पताल के कर्मचारियों और अध्ययन दल के साथ शिष्टाचार से पेश आना

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Annexure 16.37: Request for Formulation of New SOP / Revision of SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP No.	
Title:	
Details of problems or deficiency in the existing SOP	
Need to formulate an entirely new SOP (i.e., SOP not existing previously)	
Identified by:	Date (DD/MM/YYYY):
Discussed in IEC Meeting held on:	
SOP revision required: Yes No	
New SOP to be formulated: Yes No	
If yes, to be carried out by whom?	
If no, why not?	
Date SOP revised:	
Date SOP approved:	
Date SOP becomes effective:	

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Annexure 16.38: Log of IEC Members Receiving SOPs

S#	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date
1		Chairman				
2		Member Secretary				
3		Member				
4		Member				
5		Member				
6		Member				
7						
8						
9						
10						
11						
12						
13						

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

Institutional Ethics Committee
Mahatma Gandhi University of Medical Sciences & Technology
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

Annexure 16.39: EC Members Training Log

EC Members Training Log

Date: Time: Venue: *Mahatma Medical College and Hospitals, Jaipur.*
Name of Trainer:
Subject:

Sr. No.	Name of EC Members	Role in EC	Sign of Member	Evaluation Grade	Action Taken	Trainer's Sign & Date	Comment
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Grade Description:
A++ : Excellent
A+ : Good
A : Average
B+ : Fair
B : Poor

Action Taken for the Members who got B+ and B Grade
1. Re-Training on same date

Comments
Description by trainer (if required)

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Member Secretary
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Annexure 16.40: Financial Declaration of Payment Received and Disbursed

Institutional Ethics Committee Review Fees

Institutional Ethics committee (IEC) at *Mahatma Gandhi Medical College and Hospital, Jaipur-302022* shall charge an application fee for all industry sponsored human research projects.

Fee Structure

Processing fee

The EC fees for the review of a clinical Research Project is Rs.60,000/- (Rs. Sixty Thousand only). This is payable in favour of *Mahatma Gandhi University of Medical Sciences and Technology*" payable at jaipur which is the account of the Institution *Mahatma Gandhi Medical College and Hospital, Jaipur -302022.*

Compensation and Reimbursements

All external members, and experts invited (if any) will be paid an honorarium for each meeting attended and also receive re-imbursement for travel and other costs incurred towards contributing to the workings of the IEC, according to the Institutions norms.

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

Signatory of SOP approval
Member Secretary, ethics committee

Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

Institutional Ethics Committee
Mahatma Gandhi University of Medical Sciences & Technology
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Website : www.mgmch.org ; email : mgumst.ethics.committee@gmail.com

Annexure 16.41: **IEC References**

1. **World Health Organization, Operational Guidelines for IECs that Review Biomedical Research,2000.**
(Geneva 2000 www.who.int/tdr/publications/publications/-
2. **International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP)1996-**
http://www.ich.org/LOB/media/MEDIA482.pdf
3. **CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects**
http://www.cioms.ch/frame_guidelines_nov_2002.htm
4. **ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)-**
http://www.icmr.nic.in/ethical_guidelines.pdf
http://www.cdsco.nic.in/html/Schedule-Y%20 (Amended%20Version-2005)%20original.htm **5. European Convention on Human rights and Biomedicine (1997).**
http://conventions.coe.int/treaty/en/treaties/html/164.htm
6. **Code Federal Regulation Title 21**
7. **Draft Guidelines for Compensation to Participants for Research Related Injury in India.**
http://icmr.nic.in/guidelines.htm
8. **Code of Federal Regulations 45CFR46**
9. **The New Drugs and Clinical Trials Rules, 2019.** *Retrieved from https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf, accessed on September, 2021.*

Signatory of SOP approval
Member Secretary, ethics committee

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Member Secretary
Institutional Ethics Committee
MGMC, Jaipur

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Annexure 16.42: Contract and Budget Checklist

S#	Contract and Budget Elements	Please Tick
1	Is the Name of Principal Investigator, Sponsor and/ or Institution available in CTA	
2	Protocol Number and /or Title is present in the Clinical Trial Agreement	
3	Has the sponsor will pay for or provide protocol-related drugs and/or devices	
4	Is the indemnification of the PI and research Institute done by Sponsor?	
5	Insurance: is the enough insurance cover to protect	
6	Does CTA include Record retention policy as per regulatory norms	
7	Does CTA Clearly State the obligations of the PI and Sponsor/CRO, Institute (A Proforma party only)	
8	Subject Injury Reimbursement: All reasonable cost associated with the Injury related to the study drug and protocol Procedure is included in the CTA	
9	Compensation: Is CTA stated the compensation to the subject on SAE as per regulatory and applicable Guidelines	
10	Confidentiality and Non-Use: Does the CTA indicate how their medical data will be collected, used, shared, and protected.	
11	Publication: Does CTA Indicate about the trial results and research that can be published, credits that must be given upon publication, publication timeframes, and sponsorship right to review prior to publication	
12	Any other Element Please specify	

Signature of EC Member: _____

Date: _____

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Member Secretary, ethics committee

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Member Secretary
Institutional Ethics Committee
MGMC, Jaipur