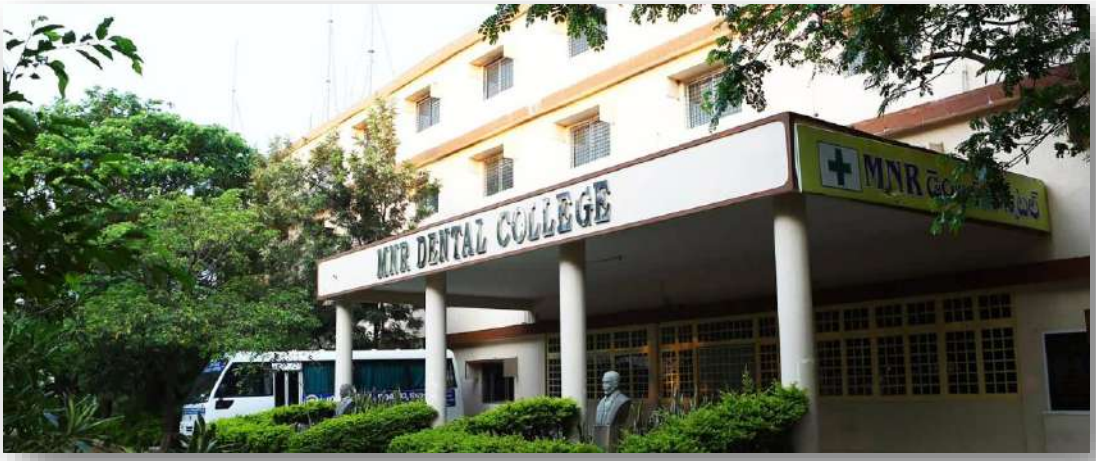

MNR DENTAL COLLEGE AND HOSPITAL

"NAAC ACCREDITED"

(Recognized by MH&FW, Govt. of India & Affiliated to KNR University of Health Sciences)

MNR Nagar, Narsapur Road, Fasalwadi, Sangareddy 502294

POLICY DOCUMENT

MNR Dental College & Hospital
Institutional Ethics Committee

TEMPLATE

Version # 2.0 effective date 1 January 2019

PRINCIPAL
MNR DENTAL COLLEGE & HOSPITAL
MNR Nagar, Narsapur Road
Sangareddy, Medak Dist.-502 294 (T.S.)

Table of Contents

HSR-401: CONFIDENTIALITY & NON-DISCLOSURE AGREEMENT

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is guidance for establishing a confidentiality and non-disclosure of information that is received during the meeting and from documents, and maintenance of privacy of research participants.
1.2. No confidential information shall be shared without prior authorization from IEC Chairperson or Organisation.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Agreement) is kept on file in the custody of the IEC.
2.5. The signed copy is given to the member.
2.6. For any questions about this document or any modifications, please contact the Organisation Official.

3. TEMPLATE

CONFIDENTIALITY & NON-DISCLOSURE AGREEMENT

In recognition of the fact, that I_____(member's name, affiliation, and address) herein referred to as the "undersigned", have been appointed as a member of MNR-Medical College & Hospital Institutional Ethics Committee, Fasalwadi Village, Narsapur-Sangareddy Road, Sangareddy District, Telangana and have been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humanely and ethically manner, adhering to the highest standards of care as per applicable regulations and guidelines, and Organisation policies.

Whereas, the appointment of the undersigned as a member of MNR-MC IEC is based on individual merits and not as an advocate or representative of state, territory or community nor as a delegate of any organisation or private interest.

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of 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 MNR Educational Trust must meet the highest ethical standards 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 behavior to carry out its mandate. This Agreement thus encompasses any information deemed confidential 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.

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 and 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.

The Undersigned agrees not to disclose or utilise, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with MNR Educational Trust policies and any contractual obligations they may have to third parties.

The undersigned maintains the confidentiality of the identification and all medical information of all participating study patients and assure security and privacy of study data.

Signature of IEC Member	Signature of Organisation Official
Name of Signatory	Name of Signatory
Residential Address	Name & Address of Organisation

4. REFERENCES

4.1. None.

HSR-402: CONFLICT OF INTEREST FORM

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is guidance for establishing real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, financial or non-financial interests pertaining to the institution and/or the individual, their family members, friends, or their professional associates.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Agreement) is kept on file in the custody of the IEC.
2.5. The signed copy is given to the member.
2.6. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Conflict of Interest Agreement Form

It is the policy of the Organisation, MNR Educational Trust; the institution, MNR Medical College & Hospital and the institutional ethics committee, MNR-MC IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested.

It is recognised that the potential for conflict of interest will always exist but has faith in the MNR-MC IEC and its Chair to manage the conflict issues so that the outcome is the protection of human subjects.

The Undersigned will immediately disclose to the Chair of MNR-MC IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

While signing the attendance register, the member documents the proposal for which he/she has Conflict of Interest. When a member has a conflict of interest, the member should notify the Chair and may not participate in IEC review or approval except to provide information requested by the Committee.

Whenever I have a conflict of interest, I shall immediately inform the IEC Chair not to count me towards a quorum for voting.

I understand that if my immediate family members or I have any direct or indirect interest in any company which has business dealings with the sponsor of the clinical study, I shall make a declaration to MNR-MC-IEC.

I would like to declare the following existing/potential* conflict of interest situation arising from the discharge of my duties concerning the sponsored clinical study or as members of the Organisation's Management Committee:

(a) *Persons/companies with whom/which I have official dealings and/or private interests :

_____

_____

(b) A brief description of my duties which involved the persons/companies mentioned in item (a) above

I, ..., have read and accept the terms mentioned above and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals if there is a conflict of interest.

Signature of IEC Member	Signature of IEC Chair
Name of Signatory	Name of Signatory
Residential Address	Name & Address of MNC-MC IEC

4. REFERENCES

4.1. HSR-002.

HSR-403: SUBMISSION COVER LETTER

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for submission cover letter to be completed by submitting investigator for review by MNR-MC IEC.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.5. An acknowledgement for receiving is given to the member.
2.6. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Submission Cover Letter to IEC

(Date of submission)

The Chair
MNR-Medical College & Hospital Institutional Ethics Committee
Fasalwadi Village
Narsapur-Sangareddy Road
Sangareddy District
Telangana

Dear Chairperson,

Subject: Application for Review of Research Study

Protocol ID:

Protocol Title:

I hereby submit to you the above-named research protocol and essential study-related documents for review by MNR-MC IEC.

I look forward to receiving any comments that you may have in relation to the above.

Thank you for your co-operation.

Sincerely,

_____

(Principal Investigator's Name & Signature)

Enclosed:

- Letter from the Head of Department
- Application Submission Form
- Study Protocol
- Informed Consent Document
- Case Report Form
- Investigator Brochure
- Questionnaire, if any
- CVs of PI and Team Members

---

4. REFERENCES

4.1. None

HSR-404: FORM FOR NOMINATING/ DESIGNATING A REVIEWER

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for nominating or designating a Reviewer.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Form for Nominating/ Designating an IEC Member for Review

<<Date>>

Ref: <<Protocol # and Title>>

Dear <<Name of IEC Member>>,

Sub: Review of <<Protocol>>/ <<Informed Consent Document>>/ <<Investigator Brochure>>

As a subject matter expert, based on your educational background and work experience, would you agree to review the following document/ section of the <<document>> that has been submitted.

- <<Name of Document>> OR <<Section # of Document>>

Thanking you, in anticipation

Sincerely,

_____
Signature of IEC Chair with date

---

4. REFERENCES

4.1. None

HSR-405: APPLICATION FORM FOR ETHICAL CLEARANCE FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for application form for review of a research study proposal by MNR-MC IEC.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated. A different format, order, or outline may be used.
2.3. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.4. An acknowledgement for receiving is given to the member.
2.5. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Application Form for Ethical Clearance of Research Involving Human Participants

Section I. ADMINISTRATION DETAILS

Date of Submission:		
Researcher's Name		
Department		
Supervisor/ Head of Department:		
Protocol Number:		
Title of Study:		
Type of research	☐ UG/ PG Academic Study	☐ Exempt Academic Study*
	☐ Staff Academic Study	☐ Regulatory Clinical Trial

*Studies that do not require CDSCO approval

For MNR-MC IEC Use:		
Reference Number	Date received:	
Review Date:	Outcome: ☐	Approval
Applicant Informed ☐ Yes ☐ No	☐	Conditional Approval
Date:	☐	Deferral
	☐	Approval Declines

Please complete form and select YES/NO options as appropriate.
An application will only be accepted for review by MNR-MC IEC if it is completed fully and the relevant enclosures are received. Complete the checklist on the next page before submitting the form. Where you have received permission to do this, please provide evidence of permission with this application.

Please ensure that all copies of the same document are collated together in sets:

- Application form
- Study Protocol
- Participant Consent Document
- CRF
- Questionnaire(s), if any
- Investigator Brochure.

Address to send application: The IEC Chair, MNR-MC Institutional Ethics Committee.

Section II. SUBMISSION CHECKLIST

Please complete the ethics application form below and provide additional information as attachments.

Application includes the following documentation:	# Copies	eCopy Yes	pCopy Yes	No	NA
• Review Application Form					
• Research Study Protocol					
• Recruitment advertisement					
• Participant Information Sheet					
• Participant Informed Consent Form					
• Questionnaire/Survey					
• Interview/Focus Group Questions					
• Case Report Form					
• Investigator Brochure					
• CVs of PI and Team Members					
• Insurance & Indemnity					
• Annex 1					
• Annex 2					
• Annex 3					

Section III. DETAILS OF DRUG/ DEVICE	Yes	No
1) Is it an Investigational New Drug/ Device (IND)?	☐	☐
2) Is it approved and marketed in		
a) India	☐	☐
b) USA/ UK/ EU/ Japan/ Australia/ Canada	☐	☐
c) Other countries:	☐	☐

3) Is a Test License obtained?				☐ ☐
Generic name (TEST)				
Trade name				
Strength		Dose		
Frequency		Route		
Generic name (Ref 1)				
Trade name				
Strength		Dose		
Frequency		Route		
Generic name (Ref 2)				
Trade name				
Strength		Dose		
Frequency		Route		

1) Who will administer the drug or fit the medical device?

2) If a medical device, has the device been through acceptance and safety testing?

3) Who is supplying the drug(s)/medical device? (If imported, name country)

4) Who will dispense the drug(s)/medical device?

Section IV. RESEARCH SPONSOR

1) Is the Sponsor?	☐ Government	☐ Commercial	☐ Non-Commercial	

2) Name and Address of Sponsor:

3) Name and Address of Indian representative, if Sponsor is outside India

4) Name and Address of Funding Agency

5) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for international collaboration? (Required in case of academic studies involving collaborations with foreign institution)	☐ Yes	☐ No	☐ NA	

Section V. STUDY DESCRIPTORS

☐ Healthy volunteers	☐ Randomised	☐ Radioactive
☐ Patient	☐ Non-randomised	☐ Biological
☐ Adult	☐ Open label	☐ Pharmaceutical
☐ Neonate	☐ Controlled	☐ Cosmetics
☐ Infant	☐ Cross-over	☐ Vaccine
☐ Children 0-12	☐ Case-study	☐ Medical device
☐ Children 13-18	☐ Placebo	☐ In vitro diagnostic kit
☐ Intervention	☐ Single-blind	☐ Ayurveda

☐ Observational	☐ Double-blind	☐ Dentistry
☐ Interview	☐ Prospective	☐ Biological tissue
☐ Questionnaire	☐ Retrospective	☐ Biological Sample
☐ Record-based	☐ Surgical	☐

Section VI. APPLICANT'S DETAILS

1) Title of Project

2) Principal Investigator (All correspondence will be sent to this address unless indicated otherwise.)

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

3) Sub-Investigator 1

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

4) Sub-Investigator 2

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

5) Clinical Research Coordinator

First Name:	Last Name:
Contact address:	MNR-FRI Clinical Trials Unit
Mobile:	Extension:
Email id	
Present appointment:	Clinical Research Coordinator
Qualification of PI:	

	Yes	No
6) Do you have any conflict of interest in the present study?	☐	☐
7) Are the team up-to-date on GCP and Regulations	☐	☐
8) Is the trial registered with CTRI	☐	☐
9) Number of protocols handled by the PI at present		

Section VII. STUDY DETAILS

Please outline, in terms that any non-expert would understand, what your research project is about, including what participants will be required to do.

10)Subject selection:	Yes	No	NA

a) Will subjects from both genders be recruited?	☐	☐	☐
b) Number of subjects to be recruited globally			
c) Number of subjects to be recruited in India			
d) Number of subjects to be recruited at MNR-MC			

11) Aim and Objectives of Study (i.e. what is the intention of the study, key research questions?)

12) Specify the primary research question/objective

13) Specify the secondary research questions/objectives

14) Scientific justification for the clinical trial?

15) What are the inclusion criteria?

16) What are the exclusion criteria?

17) What criteria exist for withdrawing research participants prematurely?

18) Scientific justification for the clinical trial?

19) Brief Study Procedure & Investigations (paste Study Flow Chart table)

20) Anticipated risks to participants (what, when, how often). Such risks could include physical stress, emotional distress, perceived coercion e.g. lecturer interviewing own students. Detail the measures and considerations you have put in place to minimize these risks.

21) Will treatment be withheld from research participants as a result of taking part in the clinical trial?	☐ Yes	☐ No
If Yes, please give details		

22) What procedures are in place to monitor the health of the research participants during the trial or when they are no longer involved in the trial?

23) What are the potential benefits for research participants?

24) Proposed start date and duration of study

Proposed start date:
Estimated close date:
Duration (months):

25) Research location and in what setting?

26) Forms of obtaining consent

☐ Audio only	☐ Paper only	☐ Assent
☐ Audio & Video	☐ AV & Paper	☐

27) Clinical phase of study

☐ Pilot investigation	☐ Phase 1	☐ Post-marketing surveillance
☐ Pivotal investigation	☐ Phase 2	☐ BA-BE
☐ Pilot performance (IVD)	☐ Phase 3	☐ Single center
☐ Pivotal performance (IVD)	☐ Phase 4	☐ Multi center

28)Does the study involve investigations and/or interventions	Yes	No
a) Self completion questionnaire	☐	☐
b) Audio/video tape recording	☐	☐

28)Does the study involve investigations and/or interventions	Yes	No
c) Physical examination	☐	☐
d) Venepuncture	☐	☐
e) Arterial puncture	☐	☐
f) Biopsy	☐	☐
g) Hospitalization	☐	☐
h) Local anesthesia	☐	☐
i) General anesthesia	☐	☐
j) Use of pre-existing/ stored/ left over biological samples		
k) Use of fetal tissue or abortus		
l) Use of organs or body fluids		
m) Use of recombinant/ gene therapy		
n) Collection for banking/ future use		
o) Use of ionizing radiation / radioisotopes		
p) Use of infectious / biohazard specimens		
q) Export of biological samples		

29)Please indicate and justify where standard of care is withheld as a result of taking part in the study

30)Data & Safety Monitoring	Yes	No	NA
a) Is a DSMB constituted by the Sponsor	☐	☐	☐
b) Is there a plan for interim analysis of data?	☐	☐	☐

Section VIII. PARTICIPANT DETAILS

31)Study population (include number overall and per site expectation)

Participants overall:
Participants from MNR-MC:

32)Will the participants be from any of the following groups? (tick as appropriate)			
☐	Children under 16	☐	Adults with learning disabilities
☐	Adults who are unconscious	☐	Adults who have a terminal illness
☐	Adults in emergency situations	☐	Adults with mental illness
☐	Pregnant women / women of child bearing age	☐	Prisoners
☐	Adults suffering from dementia	☐	Healthy volunteers
☐	Those who could be considered to be vulnerable or have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students.		
Justification for selecting a specific gender, age, or any other group, if any			

33)Will participants receive any payment or other incentives to participate, and how much?

☐ Yes	Amount to be received per visit
☐ No	

Section IX. INFORMED CONSENT	**Yes**	**No**	**NA**
34)Is written consent for participation to be obtained?	☐	☐	☐
35)Does the study include participants for whom English is not a first language?	☐	☐	☐
36)Will you inform the participants that their participation is voluntary and may be withdrawn at any point?	☐	☐	☐
37)Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	☐	☐	☐
38)Will the data be anonymous?	☐	☐	☐
39)Are women of childbearing potential included in this study?	☐	☐	☐
40)A copy of the written participant information sheet is attached	☐	☐	☐
41)Will the participant's family physician be notified of his or her participation in the trial?	☐	☐	☐
42)How long will the subject have to decide whether to take part in the study?			

43)If you are recruiting from a vulnerable group, please specify and justify:

Section X. RISKS AND ETHICAL ISSUES	**Yes**	**No**	**NA**
44)Are there are any potential risks to participants?	☐	☐	☐
a. Less than minimal risk	☐	☐	☐
b. Minimal risk	☐	☐	☐
c. More than minimal risk	☐	☐	☐
d. High risk	☐	☐	☐
45)Is this study likely to cause any discomfort or distress, either physical or mental?	☐	☐	☐
46)Is the risk reasonable compared to the anticipated benefits to subject/ community/ country?	☐	☐	☐
47)Will treatments provided during the study be available if needed at the end of the study?	☐	☐	☐

48) What particular ethical problems or issues do you consider to be important or difficult with the proposed study?

49) What arrangements have been made for research participants who might not adequately understand verbal or written information?

Section XI. FINANCIAL ARRANGEMENTS

50) What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for negligent harm? Please submit a copy of insurance.

51)Does any of the Investigator(s) in the team have any direct/indirect involvement in the outcome of the clinical trial that could in anyway be regarded as a possible conflict of interest?	☐ Yes	☐ No
52)Has funding for the clinical trial been secured?	☐ Yes	☐ No
If Yes, give details of funding organisation(s) and amount secured and duration:		
Organisation:		
Address:		
Amount:		
If No, what arrangements have been made to cover the cost of the research?		

53) The Investigator fees received, will be deposited with:

☐ Principal Investigator	☐ PI & Institution	☐ Organisation
☐ MNR-MC	☐ Department	☐ MNR-FRI

Section XII. CONFIDENTIALITY	**Yes**	**No**
54)Will the study data be held on computer?	☐	☐
55)Will paper records linking study participant ID with identifying features be stored confidentially?	☐	☐
56)Will the study team in the study examine the participants' medical records?	☐	☐
57)Will external people (auditors, monitors and inspectors) be allowed to examine medical or other personal records?	☐	☐
58)Does the proposed clinical trial involve the retention of biological material (tissue, bodily fluids) or data derived from them?	☐	☐

Section XIII. DECLARATION OF PRINCIPAL INVESTIGATOR

This declaration must be signed and sent to MNR-MC IEC together with the requisite fee before the application will be considered as valid.

- I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.

- I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in CDSCO Good Clinical Practice Guidelines and Schedule Y of the Drugs & Cosmetics Act.
- If the clinical trial is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by MNR-MC IEC.
- I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data.

Researcher	**Supervisor/Head of Department**
Signature	Signature
Name	Name
Date:	Date:

4. REFERENCES

4.1. None

HSR-406: MEETING AGENDA

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is a format for meeting agenda.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.5. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Agenda for IEC Meeting # ____

Meeting Date:

Meeting time:

Venue:

Discussion points:

1: Issues to be informed to the members

2: Discussion of the points arising from the minutes of the previous meeting

3: Presentation of agenda of the day's meeting
3.1: New Protocol Presentation, review, and discussion
3.2: Any other issues of interest to the members

IEC Chair/ Secretary
MNR-Medical College Institutional Ethics Committee
EC stamp

---

4. REFERENCES

4.1. None

HSR-407: ATTENDANCE SHEET

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is a format for tracking who attends the IEC meeting.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.5. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Attendance for IEC Meeting

MNR-MC IEC Meeting #: Date:

#	NAME	ROLE IN IEC	PHONE	SIGNATURE
1		IEC Chair/ IEC Vice-Chair		
2		IEC Secretary		
3		Basic Medical Scientist		
4		Legal Expert		
5		Social Scientist		
6		Lay person		
7		Member		
8				
9				
10				
11				

HSR-408: MINUTES OF THE MEETING

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release'
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is a format for noting the minutes of the IEC meeting.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.5. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Minutes of the MNR-MC IEC Meeting

Meeting:	<<10th MNR-MC IEC Meeting>>		
Date of Meeting: (dd/mon/yyyy)		Time:	
Minutes Prepared By:	<<Name of EC Coordinator>>	Location:	MNR-MC

1. Meeting Objective

<<Review of Following Study Protocols>>

1. Regulatory-mandated studies:
   a) Protocol # XXXX
   b) Protocol # YYYY

2. Non-regulated (academic) studies:
   a) Protocol/ Proposal # XXXX
   b) Protocol/ Proposal # YYYY

3. Review of SAE Reports
   a) Protocol # XXXX
   c) Protocol # YYYY

4. Follow-up of previous intimations

5. Protocols for continuing review:

6. Any other:

Meeting:	<<10th MNR-MC IEC Meeting>>		
Date of Meeting: (dd/mon/yyyy)		Time:	
Minutes Prepared By:	<<Name of EC Coordinator>>	Location:	MNR-MC

2. Attendance at Meeting

Name	Role in IEC	Membership	Phone
		Active	

3. Agenda and Notes, Decisions, Issues

Topic	Decision (notes in sec 4)	PI Name

4. Action Items

Action (notes)	PI	Due Date

5. Next Meeting

Date: (dd/mon/yyyy)		Time:		Location:	

4. REFERENCES

4.1. None

HSR-409: IEC DECISION LETTER

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for MNR-MC IEC decision letter that is forwarded to the submitting investigator.

2. INSTRUCTION

2.1. Delete sections which are not applicable
2.2. The suggested inclusionary elements provided in this document may be deviated.
2.3. A different format, order, or outline may be used.
2.4. The original (signed and dated Application) is kept on file in the custody of the IEC.
2.5. An acknowledgement for receiving is given to the member.
2.6. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

On IEC Letterhead

EC Ref No.: _____

Date: _____

<<Name of the PI>>
<<Designation>>
<<Department>>
<<Institution>>
<<Address>>

Dr. <<Name of the PI>>,

Subject: Decision by MNR-MC Institutional Ethics Committee for <<Protocol #>>, <<title>> and <<Name of Sponsor>>

The MNR-MC Institutional Ethics Committee in its XX meeting held on XX XXXX 2018 has reviewed and discussed your application and study-related documents in detail to conduct the above mentioned clinical trial in the department of <<Name of Dept>> with yourself as the Principal investigator.

The following study-related documents have been reviewed and <<APPROVED/ CONDITIONALLY APPROVED/ DEFERRED/ DISAPPROVED/ SUSPENDED/ TERMINATED>> in the presented form.

No.	Name of the Document	Version No. & Effective Date
1.	Investigator Brochure	
2.	Study Protocol/ Clinical Investigation Plan	

3.	Case Report Form	
4.	Participant Information Sheet	
5.	Informed Consent Form	
6.	Recruitment material, if any	
7.	Principal Investigator's CV	
8.	Insurance Cover note	
9.	Clinical Trial Agreement	
10.	Investigator's Undertaking	

The following members of the Ethics committee were present at the meeting held on (date, time and place.)

No.	Name	Qualification	Gender	Affiliation to MNR ET	Role
	Dr. X	MBBS, MD	Male	NA	Chair
1.	Dr. Y	MBBS, MD	Female	NA	Vice-Chair
2.	Dr. Z	MSc, PhD	Male	A (employee)	Secretary
3.	Mr. V	LLB	Female	NA	Member
4.					
5.					
6.					
7.					
8.					

None of the investigative team participating in this study took part in the decision-making and voting procedure for this study.

The IEC expects from the Principal Investigator to be informed about the annual progress of the study, any SAE occurring during the course of the study, any revision in the study protocol, patient information/ informed consent and be provided a copy of the final study report.

This IEC is working accordance to regulations and guidelines applicable to the functioning of the ethics committees.

Sincerely,

IEC Chair/ Secretary
MNR-Medical College & Hospital Institutional Ethics Committee

<<EC stamp>>

---

4. REFERENCES

4.1. None

HSR-410: STUDY ASSESSMENT FORM FOR EXPEDITED (QUICK) REVIEW

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for study assessment form for expedited (final ethics clearance within a short timescale) review.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.
2.3. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Request for Expedited Review

(Date of submission)

The Chair
MNR-MC Institutional Ethics Committee
Narsapur
Sangareddy District
Telangana

Dear Chairperson,

Subject: Application for Expedited Review of Research Study

Protocol #:	
Protocol Title:	

Provisional Decision		**Current Change**	
☐	Approved	☐	Updated list of study personnel
☐	Conditionally approved	☐	Required modifications are done*

*provide summary of modifications with reference to section and page number

I wish to re-submit to you the <<name of modified document>> that the IEC has requested/ inform on administrative changes in the above-mentioned research study for review by/ information of MNR-MC IEC.

I look forward to receiving an acknowledgement or comments that you may have in relation to the above.

Sincerely,

_____

(Principal Investigator's Name & Signature)

Enclosed:

- <<Name of Modified Document>>

---

4. REFERENCES

4.1. None

HSR-411: REMINDER LETTER FROM IEC TO INVESTIGATOR

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is a letter sent to the principal investigator reminding them to submit annual study report for enabling continued approval.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.
2.3. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Reminder Letter to Investigator

<<Date>>

Reference: <<Protocol ID>>

<<Name of Principal Investigator>>
<<Department>>

Dr. <<Principal Investigator>>,

The above referenced research study was approved by MNR-IEC on XX XXX XXXX and was due for Continuing Annual/ Periodic Review. You are requested to submit an Annual/ Periodic status report in the prescribed format (Continuing Review Application Form) on or before XX XXX XXXX. Please note, if the report is not submitted the last date, the IEC will cancel the approval.

Sincerely,

(IEC Chair)

---

4. REFERENCES

4.1. None

HSR-412: CONTINUING REVIEW APPLICATION FORM

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is a Continuing Review Application to be completed by the principal investigator for enabling continued approval.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.
2.3. For any questions about this document or any modifications, please contact the IEC Chair.

3. TEMPLATE

Continuing Review Application Form

Protocol #:	
Protocol Title:	
Principal Investigator:	
Department:	

Site Personnel	
Is there any change in the team since last review?	
Study Protocol Changes	
Was study Protocol/ Informed Consent Document amended since approval?	
Which version of Protocol is the site following currently	
Which version of ICD is the site following currently	
Is report of interim data analysis available	
Is the DSMB report available?	
Have any investigators developed equity or consultative relationship with the sponsor, which might be considered a conflict of interest?	
Overall Recruitment Status	
Number of participants approved	
Number of volunteers screened	
Number of participants enrolled	
Number of participants vulnerable	

Number of participants completed the study	
Number of participants dropped out (investigator decision)	
Number of participants dropped out (investigator decision)	
Number of participants dropped out (subject's decision)	
Safety	
Total number of AEs seen overall in the study (all sites)	
Total number of AEs seen at the site	
Number of AEs per participant	
Number of SAEs (overall)	
Have all the SAEs been reported to IEC?	

Investigator's Name Investigator's Signature

Date:

4. REFERENCES

4.1. None

HSR-413: TRAINING LOG

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is to record all training completed by IEC members, in addition to documented training completion certificate.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.
2.3. For any questions about this document or any modifications, please contact the IEC Chair.
2.4. Record training in the log as it is completed, to ensure completeness and accuracy of the data.
2.5. This log includes training that is documented by a completion certificate or other written documentation.
2.6. The member listed on each line should sign to verify that the training has been completed.
2.7. The Log is maintained by the EC Coordinator and filed in the Training Binder.
2.8. Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.

3. TEMPLATE

Training Log

Training Topic:
Date:
Trainer:
Venue:

IEC Member Name	Role in IEC	Signature

4. REFERENCES

4.1. None

HSR-414: WAIVER FOR OBTAINING WRITTEN INFORMED CONSENT

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is to record waiver for obtaining written informed consent.
1.2. Verbal/oral consent/waiver of consent/re-consent may be obtained under certain conditions after due consideration and approval by the EC

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.

3. TEMPLATE

Requesting Waiver Of Consent

(Date of submission)

Reference: Protocol ID number and Study Title

The Chair
MNR-Medical College & Hospital Institutional Ethics Committee
Fasalwadi Village
Narsapur-Sangareddy Road
Sangareddy District
Telangana

Dear Chairperson,

Subject: Request for waiver of informed consent:

I wish to submit a request for waiving to obtain informed consent for the above-mentioned study. The request is based on following reasons:

☐	Does not involve any investigational drug or device
☐	Research involves 'not more than minimal risk'
☐	There is no direct contact between the researcher and participant
☐	Waiver will not adversely affect the rights and welfare of the participants
☐	Research cannot practically be carried out without the waiver
☐	Waiver is scientifically justified
☐	Retrospective study, participants are de-identified or cannot be contacted
☐	Research is on anonymized biological samples/data

☐	Public health study/ surveillance program/ epidemiological/ program evaluation studies.
☐	Research on data available in the public domain
☐	Research during humanitarian emergencies and disasters, wherein the participant is not be in a position to give consent. Attempt will be made to obtain the participant's consent at the earliest.
☐	Waiver of assent (available intervention is anticipated to definitely benefit the child/ adolescent/ minor)
☐	Rights of the participants is not violated. Measures are described in the Study Protocol for protecting confidentiality of data and privacy of research participant
☐	Verbal consent is planned

I look forward to receiving an acknowledgement and IEC decision from the full committee meeting.

Sincerely,

Principal Investigator's signature with date

For MNR-MC IEC Official Use Only				
Final decision at full committee meeting held on:				
• Study Protocol meets criteria for waiver	☐	Yes	☐	No
If not granted, reasons				
Signature of Chairperson: Date:				

4. REFERENCES

4.1. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

HSR-415: STUDY MONITORING VISIT REPORT

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for reporting the findings when a designated IEC member monitors/ audit a particular study as a regulatory requirement for IEC.

1.2. This task refers to SOP Conducting Annual Tasks (HSR-125).

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.

2.2. A different format, order, or outline may be used.

3. TEMPLATE

Study Monitoring Visit Report

Date of Visit:
Type of Monitoring: ☐ Routine ☐ For-cause
Protocol No.:
Protocol Title:
Principal Investigator:
Total number of subjects enrolled:
Total subjects ongoing:
No. of dropouts :
No. of subjects completed:

1) Are there many participants who have withdrawn after administration of the first dose? ☐ Yes ☐ No
Comments for improvement (ascertain reasons for non-compliance)
2) Are site facilities appropriate? ☐ Yes ☐ No
Comments for improvement:

3) Is IEC approved Informed Consent Document of recent version used?	☐ Yes ☐ No
Comments for improvement:	
4) Whether consent has been taken from all patients?	☐ Yes ☐ No
Comments for improvement:	
5) Is the Audio-visual recording process appropriate and documented	☐ Yes ☐ No
Comments for improvement:	
6) Is confidentiality of data and privacy maintained for the participant?	☐ Yes ☐ No
Comments for improvement:	
7) Is the study protocol of recent version used?	☐ Yes ☐ No
Comments for improvement:	
8) Any adverse events, including SAE found?	☐ Yes ☐ No
Comments for improvement:	
9) Were the SAEs informed to MNR-MC IEC within 7 working days?	☐ Yes ☐ No
Comments for improvement:	

10)Are there any unanticipated increases in SAEs?	☐ Yes ☐ No
Comments for improvement:	
11) Any protocol non-compliance (deviation and violation)?	☐ Yes ☐ No
Comments for improvement:	
12)Are the randomly chosen CRFs up-to-date?	☐ Yes ☐ No
Comments for improvement:	
13) Is the investigator conducting the study as per study protocol, and applicable regulations and guidelines?	☐ Yes ☐ No
Comments for improvement:	
14) Is storage of data and investigating products locked?	☐ Yes ☐ No
Comments for improvement:	
15) How well are participants protected?	☐ Yes ☐ No
Comments for improvement:	
16) Are there any repeated reminders from sponsor to the investigator, as seen in the monitoring follow-up letters?	☐ Yes ☐ No
Comments for improvement:	

17) Any outstanding tasks or results of visit?	☐ Yes ☐ No
Comments for improvement:	

Name of the IEC representatives:

Signature:

Date:

4. REFERENCES

4.1. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

HSR-416: SUB-COMMITTEE'S REPORT ON SAE

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for reporting the decision of the designated Sub-Committee on SAE.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.

2.2. A different format, order, or outline may be used.

3. TEMPLATE

Sub-Committee's Report on SAE

Date of report:	
Protocol No.:	
Protocol Title:	
Principal Investigator:	
Total number of subjects enrolled	Total subjects ongoing:
No. of subjects completed:	No. of dropouts :
Subject ID	
Age:	Gender:
Date and time of onset of event:	
Date of reporting to IEC:	
Type of Report:	☐ Initial ☐ Follow-up
SAE Criteria	
Was the investigational product administered	
Is the blind broken	
Causality	
Recommendations	
Names of Sub-Committee members and Consultant	

4. REFERENCES

4.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

4.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

HSR-417: ARCHIVAL RECORDS INVENTORY FORM

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for documenting the IEC records that are archived.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.

3. TEMPLATE

Archival Records Inventory Form

Location of Archival	
Person archiving	
Contact person for retrieval of document	

Container #	Folder/ Item #	Description of Contents	Date of Archival

4. REFERENCES

4.1. HSR-122.

HSR-418: REQUEST TO RETRIEVE FILE FROM ARCHIVES

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for request to retrieve (accession) file from archives.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.

2.2. A different format, order, or outline may be used.

3. TEMPLATE

Request to Retrieve File from Archives

Personal Information:		
Name:		
Department:		
Address:		
Mobile:		
Email:		
For what purpose are the files required	☐	Photocopying or scanning
	☐	Prolonged perusal for research
	☐	Short, one-day perusal
	☐	Other, specify .

4. REFERENCES

4.1. HSR-122.

HSR-419: RECORDS DESTRUCTION APPROVAL FORM

Author	Dr. Sudhakar Bangera	Advisor, MNR Foundation for Research & Innovation		1 Dec 2018
	Name	**Title**	**Signature**	**Date**
Reviewer	Dr. M. Meera Bai	IEC Secretary, MNR-MC IEC		10 Dec 2018
	Name	**Title**	**Signature**	**Date**
Approver	Dr. Rakesh Sahay	IEC Chair, MNR-MC IEC		15 Dec 2018
	Name	**Title**	**Signature**	**Date**

Revision History			
Revision	**Date**	**Responsible Person**	**Description of Change**
1.0	01 September 2016	Vishwanadham Dupatla	Initial release
2.0	01 January 2019	Sudhakar Bangera	Revision to adhere to applicable regulations and guidelines

1. PURPOSE

1.1. This template is for destruction of archived IEC records.

2. INSTRUCTION

2.1. The suggested inclusionary elements provided in this document may be deviated.
2.2. A different format, order, or outline may be used.
2.3. Use this form to document records that have met or exceeded their retention period as defined in HSR-122 and are requiring destruction.
2.4. List the records to be destroyed:
  2.4.1. File name
  2.4.2. Brief description of the records (individual records need not be listed)
  2.4.3. Date, the files were retained
  2.4.4. Reason for disposal
  2.4.5. Method used to destroy the records (confidential bins, shredding, recycling, secure electronic disposal).
  2.4.6. Do not include the details of personal information in the listing.
2.5. For any questions about this form, please contact the EC Coordinator.
2.6. Note: this form is not required for the destruction of transitory records.

3. TEMPLATE

Records Destruction Approval Form

File Name	Description of Records	Retention Date Range		Reason for disposal	Destruction Method
		From	To		

Name of Approver		Signature	
Records Destroyed by (name):		Date Destroyed:	

4. REFERENCES

4.1. HSR-122.

PRINCIPAL
MNR DENTAL COLLEGE & HOSPITAL
MNR Nagar, Narsapur Road
Sangareddy, Medak Dist.-502 294 (T.S.)