OFFICE OF RUHS-CMS ETHICS COMMITTEE
RUHS COLLEGE OF MEDICAL SCIENCES, JAIPUR
(Constituent College of Rajasthan University of Health Sciences, Jaipur)
Sector-18, KumbhaMarg, Pratap Nagar, Tonk Road, Sanganer, Jaipur-302033 (Rajasthan)
Email: ruhsethicscommittee@gmail.com

Rajasthan University of Health Sciences College of Medical Sciences, Ethics Committee (HUMAN STUDIES)

PROPOSAL SUBMISSION INFORMATION

RUHS COLLEGE OF MEDICAL SCIENCES
JAIPUR, RAJASTHAN

Address for correspondence

Member Secretary
RUHS - CMS Ethics Committee
Room No: 15,RUHS College of Medical Sciences
Sector-18, KumbhaMarg, Pratap Nagar,
Tonk Road, Jaipur-302033, Rajasthan
Email: ruhsethicscommittee@gmail.com
Contact No : 09414606193, 08696443777, 07023621006

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Application Procedure

- All proposals should be submitted on any working day 4 weeks in advance of the scheduled EC meeting in the prescribed application form.(Annexure A and B).
- All relevant documents (Annexure D) should be enclosed with application form..
- Eleven copies (along with 1 soft copy in a CD) of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators/ Research Scholars and supported by the required documents shall be guided to the Chairman / Chairperson RUHS-CMS EC through Member Secretary. In case of absence of member secretary, via any person nominated by the Chairman /Chairperson. Receipt of the application will be acknowledged by the RUHS-CMS EC office.
- Also send one soft copy of the protocol on the following email address **ruhsethicscommittee@gmail.com**
- Every application will be allotted an EC proposal reference number to be used for all future correspondence and reference.
- The date of RUHS-CMS EC meeting will be intimated to the Principal Investigator, to be present, if necessary to make a brief presentation of the proposal and to clarify the points raised by the members.
- The decision of the committee on the proposal will be communicated to the Principal investigator in writing. If revision is to be made, the revised document in eleven (11) copies (along with 1 soft copy in a CD) should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
- As per government guidelines, all research proposals will need to be registered on the Clinical Trials Registry India (CTRI), National Institute of Medical Statistics, and ICMR website. The CTRI registration number and certification will have to be provided by the investigator/ sponsor prior to the initiation of the study at the time of project submission to the RUHS-CMS EC.
- In case of sponsor initiated clinical trials the Clinical Trial Agreements (CTA) the will be tripartite with signatures of Head of the Institution or his designee, Principal Investigator (PI), and the sponsor/ representative of sponsor. The head of the institute will only be "Proforma party" and all other legal and financial responsibilities and liabilities will be of the sponsor. The PI will furnish an undertaking on stamp paper of Rs. 10/- that he will abide by all the rules and byelaws then only the agreement will be signed.

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Administrative/ Processing Fee

A- All research proposals/clinical trials submitted for EC approval will be charged an administrative fee/ processing fee as specified by the Office of RUHS-CMS EC, Jaipur.

- Fees for research proposals/clinical trials funded/sponsored by Pharmaceutical companies, agencies, and multinationals will be 10% of project cost subject to minimum of Rs. 15,000.00/- per project.
- For non-funded or investigator-initiated research proposals/clinical trials, fees will be Rs. 1000/-
- Studies funded by organizations like ICMR, CSIR, UGC, State DST, DST Government of India, UNICEF, WHO, USAID, non-profitable organizations etc. fees will be Rs. 3000/- per proposal.
- For research proposals by UG candidates fees will be Rs. 500/- proposal while for PG/ Ph.D. candidates towards thesis/original research, fees will be Rs. 1000/- per proposal.

B- For re-submission of project/ proposal due to any amendment/ revision or any change, the fee structure is as follows:

- For research proposals/clinical trials funded/sponsored by Pharmaceutical companies, agencies, and multinationals, a fee of Rs. 3000.00/- will be charged per application.
- For non-funded or investigator-initiated research proposals/clinical trials fees will be Rs. 500/-
- Studies funded by organizations like ICMR, CSIR, UGC, State DST, DST Government of India, UNICEF, WHO, USAID fees will be Rs. 1000/- per proposal.
- For research proposals by UG/ PG/ Ph.D. candidates towards thesis/original research no fees will be charged.

C- For emergency meetings (any meeting conducted beyond the scheduled time on the request of sponsor/PI) :

- For research proposals/clinical trials funded/sponsored by Pharmaceutical companies, agencies, and multinationals, a fee of 15% of project cost subject to minimum of Rs. 50,000.00/- per project will be charged per application.
- For non-funded or investigator-initiated research proposals/clinical trials the fees will be Rs. 2000/-
- Studies funded by organizations like ICMR, CSIR, UGC, State DST, DST Government of India, UNICEF, WHO, USAID fees will be Rs. 5000/- per proposal.

– For research proposals by UG/ PG/ Ph.D candidates towards thesis/original research fees of Rs. 1000/- will be charged.

D- For payment of fees the candidate has to submit an application addressing to the member secretary, RUHS Ethics committee, RUHS-CMS, Jaipur regarding fee submission. The forwarded application along with the fees in then to be deposited in the account section of RUHS-CMS, Jaipur

E- In general, waiver of administrative fee is possible at the discretion of Chairman/chairperson, RUHS-CMS EC.

- **In case of sponsor initiated clinical trial**

A- The sponsor will have to furnish 10 % of project cost to the PI and co-investigator team.

B- The PI will raise invoice for trial-related expenses as per period specified in CTA and send the same to sponsor/ CRO with a copy to the office of the Principal, RUHS-CMS, Jaipur.

Review Procedure

- The meeting of RUHS-CMS EC will be held on periodic intervals, i.e. 1st Monday every three months, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required in accordance with the need of the work load.Meeting can convene only when the quorum requirements are fulfilled.
- All members shall give an undertaking declaring their conflict of interest. Regarding projects from members of RUHS-CMS EC, these members should voluntarily withdraw from the RUHS-CMS EC meeting while making a decision on that project which evokes a Conflict of Interest. This may be indicated to the chairman prior to the review and be recorded so in the minutes.
- If a member is unable to attend a meeting, he/she may submit in writing his/her opinion on the project to the chairman/chairperson before the date of the meeting. If no objection/comments are obtained from that member, projects are considered to beapproved by that member.

- Decisions will be taken by consensus of members present at the meeting after discussions, and whenever needed voting will be done. Decision of chairman /chairperson will be final.
- Researchers will be invited to offer clarifications if need be. The Principal investigator/ Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
- Minutes of the meeting will be recorded by the member secretary and will be circulated to the members and chairman/chairperson for approval.
- After the chairman/chairperson's approval is taken in writing, the comment letters signed by the member secretary will be dispatched to the applicants.

Communicating the decision

- The Member Secretary will communicate the decisions to the investigator within 10 working days of the RUHS-CMS EC meeting.
- The Member Secretary will communicate to the investigator, the decision regarding approval /modification /clarification /rejection, if any, of the research proposals, along with reasons for rejection.
- The schedule / plan of ongoing review by the EC will be communicated to the PI.

Follow up procedure for approved proposals

- EC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research. EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
- Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, EC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
- Periodic status report of study should be submitted at prescribed intervals, for review, along with information and documents as specified in Annexure-5. The prescribed interval of reporting based on safety concerns will be specified in the approval letter (Annexure 4). Final report should be submitted at the end of study.
- Following instances and events will require the follow-up review/ renewed approval:
  i. Any amendment to original protocol or consent form likely to affect rights, safety or well-being of research subject of conduct of study.

ii. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.

iii. Any event or information that may affect the benefit/risk ratio of the study.

iv. Protocol deviation, if any, with adequate justifications.

v. Any new information related to the study.

vi. Premature termination of study with reasons along with summary of the data obtained so far.

vii. Change of investigators/sites monitoring: the prescribed interval of reporting based on safety concern will be specified in the approval letter (Annexure-4).

Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the EC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.

Serious Adverse Event reporting

- Any Injury or Death of the subject occurring in clinical trials, due to following reasons, will be considered as clinical trial related injury or death:
  i. Adverse effects of Investigational Product(s);
  ii. Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
  iii. Failure of investigational product to provide intended therapeutic effect;
  iv. Use of placebo in a placebo-controlled trial;
  v. Adverse effects due to concomitant medication excluding standard care, necessitated as part of approval protocol;
  vi. For injury to a child in-utero because of the participation of parent in clinical trial;
  vii. Any clinical trial procedures involved in the study.
- The expenses on medical management and financial compensation in the case of clinical trial related injury or death of the subject will be borne by the sponsor of the clinical

trials based on the G.S.R 53(E) dated 30 Jan 2013 Rule 122DAB of Drugs & Cosmetic Rules 2013.

- Principal Investigator shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the EC within twenty four hours of their occurrence.
- The detailed report of SAE after due analysis shall be forwarded by the principal investigator to the ethics committee with a copy of the report to the licensing authority and the head of the institution, where the trail has been conducted within 10 calendar days of occurrence of SAE.

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Annexure-A

INITIAL REVIEW SUBMISSION FORM FOR RESEARCH PROPOSAL

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. CTRI Registration number and Certificate
5. Name of the Institute / Hospital / Field area where research will be conducted
6. Forwarding letter from the Head of the Department / Institution / Guide.
7. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues. **Also refer to annexure A(1)**
8. A summary of the protocol in non-technical language, synopsis or diagrammatic representation (flowchart)
9. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.
10. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available.
11. Usefulness of the project / trial
12. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any
13. Explain all anticipated ‘risks’ (adverse events, injury, discomfort) of the project. Efforts taken to minimize the ‘risks’. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.

14. Agreement to report all Serious Adverse Events (SAE) to RUHS-CMS EC.
15. Other financial issues including those related to insurance.
16. An account of storage and maintenance of all data collected during the trial.
17. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
18. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
19. Statement of conflicts of interest, if any.
20. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
21. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
22. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
23. Curriculum vitae of all the investigators with relevant publications in last five years.
24. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
25. Any other information relevant to the study.
26. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

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Annexure A (1)

LIST OF TOPIC TO BE INCLUDED IN THE PROTOCOL

1. Title

2. Introduction – Present Knowledge
   - Structural gaps
   - Need for the present Study

3. Aims & Objectives – Primary and Secondary Objectives

4. Review of Literature
   - Key Article
   - Latest Article
   - Article should be related to present study

5. Materials & Methods
   - Type of study
   - Study Design
   - Study population
   - Sample Size
   - Selection criteria of Universe & Sample
   - Inclusion & Exclusion Criteria
   - Proposed intervention if any
   - Data collection procedure & instrument used
   - Follow up schedule (if applicable)
   - Plan of analysis/Statistical tool used
6. References – In Vancover Style
7. Consent form – As per schedule Y, appendix 5, in English and Vernacular Language.
8. Participants information sheet (if applicable) as per Schedule Y, appendix 5, in English & Vernacular Language.
9. Flow Chart of the Methodology
10. Power Point Presentation should be a precise presentation of the protocol
    - Should be similar to the submitted protocol, not different from it.
    - Not exceeding 5-7 min.
    - Should consists of Introduction, Aims & Objectives, detailed methodology with a flow chart & Ethical Issues being encountered in the study.

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ANNEXURE B

Format for Submission of Projects Involving Research in Human Subjects for Clearance by RUHS-CMS EC, Jaipur

- Submit eleven (11) copies of the Research Project along with Covering letter and soft copy in a CD with the following information to the "The Member Secretary, Ethics Committee, RUHS College of Medical Sciences, Sector-18, Pratap Nagar Jaipur, Rajasthan"**.**
- The Principal Investigator must submit protocol forwarded through the Head of Department.
- No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.
- All submissions should be made in the prescribed Format of the **Ethics Committee** with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points as mentioned in Schedule Y,** before it can be considered for placing before the Institutional Ethics Committee. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received till 1stof preceding month will be processed in the coming Institutional Ethics Committee meeting and those received after 1st will be processed in the next Institutional Ethics Committee meeting. All meetings of Institutional Ethics Committee will be held as far as possible on first Monday of Jan, April, July, and October. The frequency will change depending upon the load and will be updated accordingly.
While submitting replies to queries raised by the Ethics Committee, the candidates are advised to mention the ECproposal reference number/s and also attach a copy of the comments of the Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a CD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

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Form to be filled by the Principal Investigator (PI)for submission to Ethics Committee (EC),RUHS-CMS, Jaipur

(For attachment to each copy of the proposal)

EC Proposal Reference No.:

Proposal Title:

	Name, Designation, Department & Qualification	**Address, Tel & Fax Nos., E-Mail ID**	**No. of projects already with Investigator**	**Signature**
PI				
Co-PI/ Collaborators **1.**				
2.				
3.				
4.				

5.				
6.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐
   b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget:

Who will bear the cost of investigation/implants/ drugs/contrasts?
1. ☐ Patients 2. ☐ Projects 3. ☐ Exempted
4. ☐ Other Agencies (Name)_____

1. Type of Study : Cross sectional ☐ Case control ☐ cohort ☐ Clinical Trial ☐ Review ☐

Participating Centre: Single centre ☐ Multi-centric ☐ others (Specify) ☐

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug/Vaccines/Device/Herbal Remedies:

i. Does the study involve use of:
Drug ☐ Devices ☐ Vaccines ☐
Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. is it approved and marketed In India ☐ UK & Europe ☐ USA ☐ Other countries, specify ☐		
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 is obtained? **If yes**, Date of permission:	Yes	No
iv. Is it an Investigational New Drug? **If yes**, IND No.:	Yes	No
a). Investigator's Brochure submitted	Yes	No
b). In vitro studies data	Yes	No
C). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). Are you aware if this study/similar study is being done elswhere? **If yes**, attach details	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects :

ii. Duration of study :

iii. Will subjects from both sexes be recruited	Yes	No
iv. Inclusion / exclusion criteria given	Yes	No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
fetus	☐	illiterate	☐	handicapped	☐
terminally ill	☐	seriously ill	☐	mentally challenged	☐

economically & socially backward ☐	any other ☐				
vii. Special group subjects (Tick the appropriate boxes)	Yes ☐	No ☐			
captives ☐	institutionalized ☐	employees ☐			
students ☐	nurse/dependent ☐	Armed forces ☐			
any other ☐	staff ☐				
6. Privacy and confidentiality:					
i. Study involves -	Direct Identifiers ☐				
	Indirect Identifiers/coded ☐				
	Completely anonymised/delinked ☐				
ii. Confidential handling of data by staff	Yes	No			
7. Use of biological/hazardous materials :	Yes	No			
i. Use of fetal tissue or abortus					
ii. Use of organs or body fluids	Yes	No			
iii. Use of recombinant/gene therapy	Yes	No			
if yes, has Department of Biotechnology (DBT) approval for rDNA 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. Ionizing radiation/radioisotopes	Yes	No			
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been otbained?	Yes	No			
vii. Use of Infectious/bio hazardous speciments	Yes	No			
viii. Proper disposal of material	Yes	No			
ix. Will any sample collected from the patients be sent abroad? **If yes, justify with details of collaborators**	Yes	No			
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No			
b) Sample will be sent abroad because (Tick appropriate box):					
Facility not availabe in India ☐					
Facility in India inaccessible ☐					
Facility availabe but not being accessed. ☐					

If so, reasons.....

8. Consent: *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact Information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization	☐
Compensation for study related injury	☐	eg. Genetic basis for drug development	☐

* If written consent is not obtained, give reasons:

ii. Who will obtin consent? PI/Co-PI ☐ Nurse Counsellor ☐ Research Staff ☐ Any other ☐

9. Will any advertising be done for recruitment of subjects? (posters, fllyers, brochure, websites- if so kindly attach a copy)	Yes	No
10. 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? **If yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
iii. Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee / Board (DSMB) ?	Yes	No
ii. Is there a plan for reporting of adverse events?	Yes	No

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If Yes, reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐		
iii. Is there a plan for interim analysis of data?	Yes	No
iv. Are there plans for storage and maintenance of all trial database? **If Yes**, for how long?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify:**	Yes	No
Conflict of interest for any other Investigator(s) (if yes, please explain in brief)	1_____Yes No 2_____Yes No 3_____Yes No 4_____Yes No	
15. Participant Information Sheet *(mark √ if yes)*	☐ Attached English Version ☐ Attached Hindi Version ☐ Certified that Hindi version is a true translation of English version	
16. Participant Informed consent form *(mark √ if yes)*	☐ Attached English Version ☐ Attached Hindi Version ☐ Certified that Hindi version is a true translation of English version	
17. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* (Please enclose a separate certificate to this effect)	
18. In case of clinical trials CTRI status		

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ANNEXURE C
UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

   Education, training & experience that qualify the Investigator for the clinical trial (Attach details includingMedical Council registration number, and / or any other statement(s) of qualification(s))
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:
   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conductthe study. I will not begin the study until all necessary Ethics Committee and regulatory approvals havebeen obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviationfrom or changes of the protocol without agreement by the Sponsor and prior review and documentedapproval / favorable opinion from the Ethics Committee of the amendment, except where necessary toeliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical oradministrative in nature.
   iii. I agree to personally conduct and/or supervise the clinical trial at my site.
   iv. I agree to inform all Subjects that the drugs are being used for investigational purposes and I willensure that the requirements relating to obtaining informed consent and ethics committee review andapproval specified in the GCP guidelines are met.
   v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) inaccordance with the regulatory and GCP guidelines.
   vi. I have read and understood the information in the Investigator's brochure, including the potential risksand side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study aresuitably qualified and experienced and they have been informed about their obligations in meeting theircommitments in the trial.

viii. 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, inaccordance with regulatory and GCP provisions. I will fully cooperate with any study related auditconducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and allunanticipated problems involving risks to human Subjects or others.

x. I agree to inform all unexpected serious adverse events to the Sponsor, Licensing Authority, Head of the Department, and the Ethics Committee within 24 hours of their occurrence and will submit a detailed report to the IEC and Licensing authority within 10 days of their occurrence.

xi. I will maintain confidentiality of the identification of all participating study patients and assure securityand confidentiality of study data.

xii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable toclinical Investigators participating in clinical trials

Signature of Investigator:

Date:

OFFICE OF RUHS-CMS ETHICS COMMITTEE
RUHS COLLEGE OF MEDICAL SCIENCES, JAIPUR
(Constituent College of Rajasthan University of Health Sciences, Jaipur)
Sector-18, KumbhaMarg, Pratap Nagar, Tonk Road, Sanganer, Jaipur-302033 (Rajasthan)
Email: ruhsethicscommittee@gmail.com

Annexure-D

Proposal Submission Checklist

Project Title: _____

Sr. No.	Documents Required for Submission	# of Copies	Please Tick(√)
1.	a. Final Copy of Protocol b. Brief description of proposal in about 500 words c. Summary of protocol in non-technical language, synopsis or diagrammatic representation	11	
2.	Final Copy of Investigators Brochure	1	
3.	Copy of Patient Information sheet and Informed Consent Form (English)	11	
4.	Copy of Patient Information sheet and Informed Consent Form (Hindi / Local Language)	11	
5.	Copy of the back translated Patient Information sheet and Informed Consent Form from Hindi to English.	1	
6.	Translation & Back Translation Certificate	1	
7.	Undertaking by the Investigator (as described in Appendix VII of Schedule Y)	1	
8.	Copy of the Case Report Form	11	
9.	Approval/ submission Letter from the Drugs Controller General of India (if applicable)	1	
10.	Copy of draft/ final Clinical Trial Agreement, if applicable	1	
11.	Current signed CV of the Principal Investigator and Co-investigators	1	
12.	Copy of Insurance and Indemnification Policy for the investigator/institution, if applicable	1	
13.	Global Regulatory approvals, if available	1	
14.	IEC approvals from other sites, if applicable	1	
15.	EC Fees (as per EC - SOP) payable at Jaipur, as applicable	1	
16. a	Cover Letter from Investigator for fee submission.	1	
16. b	Cover Letter from Investigator for protocol Submission	1	
17.	Copy of CTRI registration number, if applicable	1	
18.	Soft copy of all the documents submitted for review in CD/DVD	1	

Note: Registration from CTRI (Clinical Trial Registry of India) is mandatory for the conduct of trial.

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ANNEXURE - E
FORMAT FOR ANNUAL PROGRESS REPORT

1. Project title
2. PI (name & address)
3. Co-PI (name & address)
4. Date of start
5. Duration
6. Objectives of the proposal
7. Methodology
8. Interim modification of objectives/methodology (with justifications)
9. Summary on progress (during the period of report)
10. Applied value of the project
11. Research work which remains to be done under the project
12. Any publications.
13. Any patents applied for
14. If additional budget or staff is required for the remaining part of the research work, please give justifications and details.

Date :

Signature

Designation

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Annexure- F

Data Elements for reporting serious adverse events occurring in a clinical trial

1. *Patient Details*
   Initials & other relevant identifier (hospital/OPD record number etc.)*
   Gender
   Age and/or date of birth
   Weight
   Height

2. *Suspected Drug(s)*
   Generic name of the drug*
   Indication(s) for which suspect drug was prescribed or tested
   Dosage form and strength
   Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
   Route of administration
   Starting date and time of day
   Stopping date and time, or duration of treatment

3. *Other Treatment(s)*
   Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. *Details of Suspected Adverse Drug Reaction(s)*
   Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*
   Start date (and time) of onset of reaction
   Stop date (and time) or duration of reaction
   Dechallenge and rechallenge information
   Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. *Outcome*
   Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.
Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. *Details about the Investigator**
   Name
   Address
   Telephone number
   Profession (specialty)

   Date of reporting the event to Licensing Authority:
   Date of reporting the event to Ethics Committee overseeing the site:

Note: Information marked * must be provided."

Signature of the Investigator