OFFICE OF RUHS CMS-ETHICS COMMITTEE
R.U.H.S. COLLEGE OF MEDICAL SCIENCES, JAIPUR
(Constituent College of Rajasthan University of Health Sciences, Jaipur)
Sector-11, KumbhaMarg, Pratap Nagar, Tonk Road, Sanganer, Jaipur 302033 (Rajasthan)
Email: ruhsethicscommittee@gmail.com

RUHS CMS-ETHICS COMMITTEE PROPOSAL SUBMISSION INFORMATION

RUHS COLLEGE OF MEDICAL SCIENCES JAIPUR, RAJASTHAN

Address for correspondence
Member Secretary
RUHS CMS-Ethics Committee
IInd Floor, Department of Community Medicine
RUHS College of Medical Sciences
Sector-11, KumbhaMarg, Pratap Nagar,
Tonk Road, Jaipur-302033, Rajasthan
Email: ruhsethicscommittee@gmail.com
Contact No: 09414606193, 08696443777, 07597076210

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APPLICATION PROCEDURE

- All proposals should be submitted on a working day,4 weeks in advance of the scheduled EC meeting in the prescribed application form. (Annexure 2 and 3)
- All relevant documents (Annexure 4)should be enclosed with the application form.
- Fifteen copies (along with 1 soft copy in a CD) of the research protocol along with the application form duly signed by the Principal Investigator (PI) and co-investigators/ collaborators/research scholars and supported by the required documents shall be guided to the chairperson RUHS CMS-EC through member secretary. In case of absence of member secretary, via any person nominated by the chairperson. Receipt of the application will be acknowledged by RUHS CMS-EC office. (Annexure 5)
- Every application will be allotted an EC proposal reference number (EC PRN) to be used for all future correspondence and reference.
- The date of RUHS CMS-EC meeting will be intimated to the PI, 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 PI in writing. If revision is to be made, the revised document in fifteen (15) copies (along with 1 soft copy in a CD) should be submitted within a stipulated period of time as specified in the letter of 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 proposal submission to RUHS CMS-EC.
- ***In case of sponsor initiated clinical trials***, the Clinical Trial Agreements (CTA), that will be tripartite with signatures of Head of the Institution or his designee, Principal Investigator (PI), and the sponsor/representative of sponsor should be submitted. 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 RUHSCMS-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/-
- For 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/-
- For 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/-
- For 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.

In case of sponsor initiated clinical trial, the sponsor will have to furnish 10 % of project cost to the PI and co-investigator team. 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.

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

For payment of fees, the principal investigator will submit an application for fee submission to the Member Secretary, RUHS CMS-Ethics Committee, Jaipur. The fees will then be deposited in the Accounts Section, Administrative Block, RUHS-CMS, Jaipur along with theduly signed and forwarded application.

Review Procedure

- The meeting of RUHS CMS-EC will be held quarterly i.e. 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.
- The member secretary shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review. (Annexure 14)
- A researcher cannot decide that her/his proposal falls in the exempted, expedited, or full review category. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited, or if waiver of consent is requested.
- Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members.
- Approval granted through expedited review and the decisions on SAE will be ratified at the next full committee meeting.
- RUHS CMS-EC may have a system of appointing primary and secondary reviewers. The member secretary will identify the primary and secondary reviewers for reviewing the

scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.

- The member secretary may identify subject experts to review the proposal as per need. These experts may be invited to the EC meeting or join via video/teleconference but will not participate in final decision making.
- All members shall give an undertaking declaring their conflict of interest. If a member has declared a COI for a proposal then this should be submitted in writing to the chairperson before beginning the meeting and should be recorded in the minutes. The member who has declared COI should voluntarily withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This should be minuted and the quorum rechecked.
- A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.
- If a member is unable to attend a meeting, he/she may submit in writing his/her opinion on the project to the chairperson before the date of the meeting. If no objection/comments are obtained from that member, projects are considered to be approved 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 chairperson will be final.
- The researcher may be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but should not be present at the time of decision making. 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 chairperson for approval.
- The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review should be ratified.
- After the chairperson's approval is taken in writing, the letters of communication, 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 RUHS CMS-EC meeting.
- The member secretary will communicate to the investigator the decision regarding approval/modification/clarification/rejection, if any, of the research proposal, along with reasons for rejection.

- The schedule/plan of ongoing review by the EC will be communicated to the PI.
- The researcher will have an opportunity to reply/clarify to EC comments or to discuss or present her/his stand.
- The researcher can also approach the head of the institute who serves as an appellate for EC matters.

Continuing Review

- RUHS CMS-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.
- Progress report/completion report of study should be submitted at prescribed intervals, for review, along with information and documents as specified in Annexure 7 and 8.The prescribed interval of reporting based on safety concerns will be specified in the approval letter (Annexure6). 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 participant of the 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 6).

Site 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

- Research participants who suffer direct physical, psychological, social, legal, or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.
- The researcher is responsible for reporting all SAEs to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days.
- The EC is responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants.
- For clinical trials under the purview of CDSCO, the timeline and procedures as notified from time to time may be followed.
- All research participants who suffer harm, whether related or not, should be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc.
- Medical management should be free if the harm is related to the research.
- Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.
- While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC should consider aspects including the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc.
- For other sponsored research, it is the responsibility of the sponsor (whether a pharmaceutical company, government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.

- In investigator initiated research/student research, the investigator/institution where the research is conducted becomes the sponsor.
  - It is the responsibility of the host institution to provide compensation and/or cover for insurance for research related injury or harm to be paid as decided by the EC.
  - The institution should create in-built mechanism to be able to provide for compensation, such as a corpus fund in the institution.
- In the applications for research grants to funding agencies–national or international, government or non-government agencies– the researcher should keep a budgetary provision for insurance coverage and/or compensation depending upon the type of research, anticipated risks and proposed number of participants.

For Clinical Trials

- 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.

Ancillary care

Participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC.

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ANNEXURE 2

General Instructions

- Submit fifteen (15) copies of the protocol of research proposal along with a covering letter, a soft copy in a CD, and the required documents to the "The Member Secretary, Ethics Committee, RUHS College of Medical Sciences, Sector-11, Pratap Nagar Jaipur, Rajasthan"**.**
- The Principal Investigator must submit the research proposal forwarded through the Head of Department.
- No research proposal 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 RUHS CMS 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 RUHS CMS-Ethics Committee. Also ensure that all the pages are numbered.

Proposal Submission Time: Submissions will be received on all working days. Proposals received till 1st of preceding month will be processed in the coming Institutional Ethics Committee meeting and those received after 1stwill 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 raised by the Ethics Committee, the candidates are advised to mention the EC proposal 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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RESEARCH PROPOSAL SUBMISSION FORM

EC Proposal Reference No.:
(For office use only)

Research Proposal Title:_____

_____

_

_____

_

Name of the Institute/Hospital/Field area where research will be conducted _____

_____

1. Investigators Details:				
	Name, Designation, Department and 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

2. Sponsor Information (attach the relevant document/s)	
A. National:	***a) Government:*** 1. Central 2. State3. Institutional ***b) Private***
B. International:	a. Government b. Private c. UN agencies
C. Industry:	a. National b. Multinational
D. Contact Address of Sponsor:	

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E. Total Budget (attach relevant document/s)	
F. Who will bear the cost of investigation/implants/drugs/contrasts?	a. Patients b.Projects c.Exempted d. Other Agencies (Name)_____

3. Type of Study :

a. Cross sectionalb. Case controlc. Cohortd. Clinical Triale. Review

f. Others (Specify) _____

Participating Centre: a. Single centreb. Multi-centric

4. Status of Review:a. Newb. Revised

5. Clinical Trials:

A. Does the study involve use of:

a. Drug b. Device c.Indian Systems of Medicine/Alternate System of Medicine

d. Vaccines e. Any other

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B. Is it approved and marketed in: a. India b. UK & Europe c. USA d. Other countries, specify _____		Yes Yes Yes	No No No
C. Does it involve a change in use, dosage, route of administration? **If yes**, whether DCGI's/Any other regulatory authority's permission is obtained? **If yes**, Date of permission: _____		Yes Yes	No No
D. Is it an Investigational New Drug? **If yes**, IND No.: _____		Yes	No
a.	Investigator's Brochure submitted (attach the document)	Yes	No
b.	In vitro studies data (attach the document)	Yes	No
c.	Preclinical Studies done (attach the document)	Yes	No
d.	Clinical Study is in: a. Phase I b. Phase II c. Phase III d. Phase IV		

E. Are you aware if this study/similar study is being done elswhere? **If yes**, attach details	Yes	No
6. Protocol of the proposed research (attach 15 copies)		
7. Participant selection: i.Number of Participant:		
ii. Duration of study:		
iii.Will participants from both sexes be recruited	Yes	No

iv.Inclusion/exclusion criteria given	Yes	No
v. Type of participant:a. Volunteersb. Patients		
vi.Vulnerable participants: a. Yesb. No (Tick the appropriate) 1. Pregnant women2. Children3. Elderly 4. Fetus 5. Illiterate6. Handicapped 7. Terminally ill 8. Seriously ill 9. Mentally Challanged 10. Economically and Socially Backward 11. Any Other _____		
vii.Special group participants a. Yesb. No (Tick the appropriate) 1. Captives2. Institutionalized3. Employees4. Students 5. Nurse/dependent6. Armed forces7.Staff8. Any Other		
8.Privacy and confidentiality: i.Study involves: a. Direct Identifiers b. Indirect Identifiers/coded c. Completely anonymised/delinked		
ii.Confidential handling of data by staff	Yes	No
9.Use of biological/hazardous materials : i.Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No

iii.Use of recombinant/gene therapy **If yes**, has Department of Biotechnology (DBT) approval for rDNA products been obtained?		Yes Yes	No No
iv.Use of pre-existing/stored/left over samples		Yes	No
v. Collection for banking/future research		Yes	No
vi. Ionizing radiation/radioisotopes **If yes**, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been otbained?		Yes Yes	No 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): a. Facility not availabe in India b. Facility in India inaccessible c. Facility availabe but not being accessed. If so, reasons _____		

10. Consent: **a.***Written b. Oral c. Audio-visual

* If written consent is not obtained, give reasons: _____

i. Consent form : (tick the included elements)	
a. Understandable language	i.Alternatives to participation
b. Statement that study involves research	j.Confidentiality of records
c. Sponsor of study	k.Contact Information
d. Purpose and procedures	l.Statement that consent is voluntary
e. Risks & Discomforts	m.Right to withdraw
f. Benefits	n.Consent for future use of biological material
g. Compensation for participation	o.Benefits if any on future commercialization
h. Compensation for study related injury	eg. Genetic basis for drug development

ii.Who will obtain consent?1. PI/Co-PI2. Nurse Counsellor

3.Research Staff4. Any other _____

11.Will any advertising be done for recruitment of subjects? (posters, fllyers, brochure, websites- if so kindly attach a copy)	Yes	No
12.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,a.** Minimal or no risk b. More than minimum risk c. High risk	Yes	No

iii. Is there: a. A benefit to the subject? A. DirectB. Indirect

b. Benefit to the society?

13.Data Monitoring i.Is there a data & safety monitoring committee / Board (DSMB) ?	Yes	No

ii.Is there a plan for reporting of adverse events? **If Yes**, reporting is done to : A. SponsorB. Ethics CommitteeC. DSMB	Yes	No
iii.Is there a plan for interim analysis of data?	Yes	No
iv.Are there plans for storage and maintenance of all research database? **If Yes**, for how long? _____	Yes	No
14.Is there compensation for participation? **If Yes,A.** Monetary**B.** In kind Specify amount and type:_____	Yes	No
14.Is there compensation for injury? **If Yes,A.** by sponsorB. by Investigator C. by insurance company D.by any other	Yes	No
15. Do you have conflict of interest?(financial/nonfinancial)	Yes	No
If Yes, specify: _____ Conflict of interest for any other Investigator(s) (if yes, please explain in brief)		
16. Participant Information Sheet*(mark √ if yes)* A. Attached English Version B. Attached Hindi Version C. Certified that Hindi version is a true translation of English version		
17. Participant Informed consent form*(mark √ if yes)* A. Attached English Version B. Attached Hindi Version C. Certified that Hindi version is a true translation of English version		

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18.Whether any work on this project has started or not? (Please enclose a separate certificate to this effect)	**Yes/ No**
19.CTRI status	
20. 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.	
21. Source of funding and financial requirements for the project.	
Any other information relevant to the study	

Signature of PI:

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ANNEXURE 3

DETAILS TO BE INCLUDED IN THE PROTOCOL OF RESEARCH PROPOSAL

The protocol should include the following:

1. The face page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary;
3. Background with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research objectives and end points (if applicable);
6. Eligibility criteria and participant recruitment procedures;
7. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
8. Duration of the study;
9. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;
10. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;
11. Plan for statistical analysis of the study;
12. Plan to maintain the privacy and confidentiality of the study participants;
13. For research involving more than minimal risk, an account of management of risk or injury;
14. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
15. Provision of ancillary care for unrelated illness during the duration of research;
16. An account of storage and maintenance of all data collected during the research; and
17. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
18. Ethical considerations and safeguards for protection of participants.

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ANNEXURE-4

CHECKLISTFOR DOCUMENTS TO BE SUBMITTED FOR EC REVIEW

Sr. No.	Documents Required for Submission	No. of Copies	Please Tick(√)
1.	Cover Letter from Investigator for research proposal submission	01	
2.	Cover Letter from Investigator for fee submission	01	
3.	EC Fees receipt (as per RUHS CMS-EC SOP) payable at Jaipur, as applicable	01	
4.	Application form for initial review (Annexure 2)	1	
5.	1. Summary of the protocol in non-technical language/ synopsis/ diagrammatic representation	15	
	2. Protocol of the research proposal	15	
	3. Seed article	15	
6.	Investigator's brochure (as applicable for drug/biologicals/device trials)	15	
7.	The correct version of Informed Consent Form (ICF) in English	15	
8.	The correct version of Patient/Participants Information sheet (PIS) Form in English		
9.	Copy of Informed Consent Form (ICF) in Hindi/Local Language	15	
10.	Copy of Patient Information sheet (PIS) in Hindi/Local Language	15	
11.	Copy of Assent Form, if applicable in English	15	
12.	Copy of Assent Form, if applicable in Hindi/ Local Language	15	
13.	Copy of the back translated Patient Information sheet and Informed Consent Form from Hindi to English.	15	
14.	Translation & Back Translation Certificate	01	
15.	Undertaking by the Investigator (Annexure 10)	01	
16.	Copy of the Case Report Form/ Questionnaire	15	
17.	Recruitment procedures of subjects: advertisement, notices, etc. (if applicable)	15	
18.	GCP training certificate (preferably within 5 years) of investigators (clinical trials)	01	
19.	Approval/ Submission Letter from the Drugs Controller General of India (if applicable)	01	
20.	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	01	

	Drug Controller General of India (DCGI)		
21.	For exchange of biological material in international collaborative study a MoU/Material Transfer Agreement between the collaborating partners	01	
22.	Copy of draft/ final Clinical Trial Agreement, if applicable	15	
23.	Current signed CV of all the study researchers	01	
24.	List of ongoing research studies undertaken by the principal investigator (if applicable)	01	
25.	Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)	15	
26.	Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)	15	
27.	Global Regulatory approvals, if available	01	
28.	IEC approvals from other sites, if applicable	01	
29.	Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)	01	
30.	MoU in case of studies involving collaboration with other institutions (if applicable)	01	
31.	Statement on conflict of interest, if any	01	
32.	Copy of CTRI registration number, if applicable	01	`
33.	Soft copy of all the documents submitted for review in CD/DVD (and also e-mail it at ruhsethicscommittee@gmail.com)	01	

Note: Registration from CTRI (Clinical Trial Registry of India) is mandatory for the conduct of Research in Human Subjects

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ANNEXURE 7

FORMAT FOR PROGRESS REPORT

To,

The Member Secretary,
RUHS CMS Ethics Committee
Sector-18, Kumbha Marg, Pratap Nagar, Tonk Road,
Jaipur-302033 (Rajasthan), India

Protocol Title:
Subject: Submission of Progress Report
Reference: Your Approval letter no._____dated _____

Respected Sir,

Please find below the progress report of the above referenced study

1. PI (name & address):
2. Co-PI (name & address):
3. Date of RUHS CMS-EC Approval:
4. Date of start of the study:
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):
    a. Date of First Subject Enrollment:
    b. Date of Last Subject Enrollment:
    c. Total Number of subjects screened till date:
    d. Total Number of subjects completed till date:
    e. Total Number of Adverse Events till date:
    f. Total Number of Serious Adverse Events till date:
    g. Total Number of Deaths till date:
    h. Total Number of Subjects withdrawn till date:
11. Applied value of the project
12. Research work which remains to be done under the project
13. Any publications.
14. Any patents applied for (if applicable)

Sincerely
Name and Designation of Principal Investigator

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ANNEXURE 8

FORMAT FOR FINAL REPORT

1. Title of the Project:
2. Principal Investigator and Co-Investigators :
3. Implementing Institution and other collaborating Institutions:
4. Date of commencement:
5. Duration:
6. Date of completion:
7. Objectives as approved:
8. Deviation made from original objectives if any, while implementing the project and reasons thereof.
9. Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams and photographs.
10. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.
11. Conclusions summarizing the achievements and indication of scope for future work.
12. List of research publications with complete details: Authors, Title of paper, Name of Journal, Vol., page, year
13. Manpower trained on the project:
    a. Research Scientists or Research Fellows
    b. No. of PhDs produced
    c. Other Technical Personnel trained
14. Patents taken, if any:
15. Products developed, if any.

(Name and signature with date)

1. _____ (Principal Investigator)
2. _____ (Co-Investigator)

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ANNEXURE 10
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 research proposal will be conducted:
   (Education, training & experience that qualify the Investigator for the research/ clinical trial (Attach details including Medical 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 research/ 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 conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
   ii. 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.
   iii. I agree to personally conduct and/or supervise the research/ clinical trial at my site.
   iv. 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.
   v. 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.
   vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. 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.

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, 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.

ix. I agree to promptly report to the Ethics Committee all changes in the research/clinical trial activities and all unanticipated 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 security and confidentiality of study data.

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

Signature of Investigator:

Date:

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ANNEXURE 11

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL

1. **Patient Details**
   Initials and 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

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ANNEXURE 12
INFORMED CONSENT

An informed consent form must include the following:

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

In addition, the following elements may also be required, depending on the type of study:

1. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected
2. If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pretest- and post-test counseling.
3. Insurance coverage if any, for research-related or other adverse events
4. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research.

Other specifics are as follows:

i. Period of storage of the sample/data and probability of the material being used for secondary purposes.

ii. Whether material is to be shared with others, this should be clearly mentioned.
iii. Right to prevent use of her/his biological sample, such as dna, cell-line, etc., and related data at any time during or after the conduct of the research.
iv. Risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.
v. Post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.
vi. Publication plan, if any, including photographs and pedigree charts.

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ANNEXURE 13

CONTENT OF ASSENT FORM

- For children less than 7 years of age, parental consent is sufficient.
- For children between 7 (84 months and above) and 11 years of age, oral assent must be obtained in the presence of parent/LAR.
- For children between 12 and 18 years of age, written assent must be obtained.
- If a child becomes 13 years old during the course of the study, then written assent must be obtained in addition to parent/LAR consent.
- This is a joint decision-making process between the child and the concerned adult. In cases of verbal assent, the parent /LAR's countersignature must be obtained confirming that the child's verbal assent has been taken. Re-assent must be taken in all the same situations as re-consent.
- As assent is part of the informed consent process, the regulations as per the CDSCO guidelines for regulatory clinical trials apply for assent as well.
- The type and amount of information given needs to be simplified as per the child's cognitive and developmental level. The information should be simple, and age-appropriate.

The basic information that needs to be provided includes:

1. What the study is about and how it might help We want to see whether a new medicine will or won't help children like you who have skin rashes" "We want to understand why children get tummy aches, like you do"

2. What will happen and when "You will have to come to the hospital in the morning with an empty stomach. We will insert a needle and take a teaspoonful of blood"

3. What discomfort there might be and what will be done to minimize it "It will hurt as much as a pin prick, but the pain will last only 5 minutes. The area may look red for some time"

4. Who will answer the child's questions during the study If you have any questions at any time, you can ask Dr. X."

5. Whether an option to say "no" exists "You can say "no" if you don't wish to take part in the study. No one will be angry with you." "If you say "yes" and then change your mind later, it will be fine. No one will scold you"

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ANNEXURE 14
Participant Information sheet template

The following is a suggested template for participant information sheets. You should adjust and populate the template to suit your project and intended audience. Use clear, simple language at all times easily understandable by 5th standard child and avoid abbreviations and acronyms.

[**TITLE OF THE STUDY**]: The title should be clear, self-explanatory and consistent across all documents referring to the study.

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

Explain who you are and why you are doing this study. Explain the overall aim of the study. When describing the study take care to be as neutral as possible and avoid suggesting any bias about what you expect the outcomes from the research to be. If the research is being undertaken as part of a course of study state what qualification will result from the process.

WHAT WILL TAKING PART INVOLVE?

Explain what taking part in the research will involve including a list of topics that you will discuss and the expected location and duration of participation. If you plan to use audio recording discuss that also.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

Explain why you have selected this particular individual to take part in your research and how you came to select them.

DO YOU HAVE TO TAKE PART?

Explain that participation is completely voluntary and that the person has the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Give a frank and realistic assessment of the possible benefits of the research – do not oversell what the research will achieve. Consider any possible physical or psychological harm that may

come to a participant as a result of participating in the research and what you will do should such a situation arise.

WILL TAKING PART BE CONFIDENTIAL?

Explain what steps you will take to ensure the confidentiality and anonymity of the participant and any individuals they talk about. Outline the situations in which you may have to break confidentiality: if the researcher has a strong belief that there is a serious risk of harm or danger to either the participant or another individual (e.g. physical, emotional or sexual abuse, concerns for child protection, rape, self-harm, suicidal intent or criminal activity) or if a serious crime has been committed. You should also make it clear that non-anonymised data in the form of signed consent forms and audio recordings are collected and retained as part of the research process.

HOW WILL INFORMATION YOU PROVIDE BE RECORDED, STORED AND PROTECTED?

Explain that the interview will be recorded and outline the arrangements for storing the research data (where it will be stored, security arrangements, who will have access). Also outline the relevant data retention policy. This will vary depending on the nature and needs of your project (see the Research Ethics Committee website for further information). For students undertaking Masters programmes who have no intention of subsequently publishing their research the relevant paragraph should read:‘ Signed consent forms and original audio recordings will be retained in [specify location, security arrangements and who has access to data] until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation you are entitled to access the information you have provided at any time.’

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Outline fully and realistically your plans for the dissemination of the final research product including conferences, publications and teaching use. If your plans for the research only consist in submitting your dissertation then simply state this.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Provide the name, affiliation and contact details of all researchers involved as well as supervisor details where relevant.

[THANK YOU]

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