

Covering Letter

Date:

To
The Chairperson/Member Secretary,
Institutional Ethics Committee,
Sai Tirupati University,
Udaipur (Raj.)

Sir/Madam,

I/we submit hereby documents related to the following RESEARCH PROPOSAL for approval by Institutional Ethics Committee.

Title of the research study is,

Name of Chief-Investigator:

Designation:

Site of Research:

Name of Guide/Co-investigator:

Designation:

Thanking you,

Yours sincerely,

Signature of HOD

(Chief Investigator)



Application Form for Initial Review

(Biomedical and Health Research)
Institutional Ethics Committee, Sai Tirupati University

EC Ref. No.....

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

(b) Name of Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of submission: dd mm yy

(f) Type of review requested¹:

Exemption from review Expedited review Full committee review

(g) Title of the study:

Acronym/ Short title, (If any):

(h) Protocol number (If any): Version number:

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication ²
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission

ii) Co-Investigator at time of submission:

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.....

(k) Duration of the study:

¹Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review

²Include telephone/mobile, fax numbers and email id

(b) Is there an external laboratory/outsourcing involved for investigations?⁴ Yes No NA

(c) How was the scientific quality of the study assessed?

Independent external review Review by sponsor/Funder Review within PI's institution

Review within multi-centre research group No review

Date of review:

dd	mm	yy
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Comments of scientific committee, if any (100 words)

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SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers Patients Vulnerable persons/ Special groups

Others (Specify)

Who will do the recruitment?

Participant recruitment methods used:

Posters/leaflets/Letters TV/Radio ads/ Social media/ Institution website Patients / Family/Friends visiting hospitals Telephone

Others (Specify)

(b) i. Will there be vulnerable persons / special groups involved ? Yes No NA

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs Pregnant or lactating women

Differently abled (Mental/Physical) Employees/Students/Nurses/Staff

Elderly Institutionalized

Economically and socially disadvantaged Refugees/Migrants/Homeless

Terminally ill (stigmatized or rare diseases)

Any other (Specify):

iii. Provide justification for inclusion/exclusion

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.....

iv. Are there any additional safeguards to protect research participants?.....

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.....

⁴If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU

(c) Is there any reimbursement to the participants? Yes No

If yes, Monetary Non-monetary Provide details

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.....

(d) Are there any incentives to the participants? Yes No

If yes, Monetary Non-monetary Provide details

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(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary Non-monetary Provide details Yes No

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6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes No

If yes, categorize the level of risk⁵ :

Less than Minimal risk Minimal risk

Minor increase over minimal risk or low risk More than minimal risk or high risk

ii. Describe the risk management strategy:

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.....

(b) What are the potential benefits from the study? Yes No If yes, Direct Indirect

For the participant

For the society/community

For improvement in science

Please describe how the benefits justify the risks

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(c) Are adverse events expected in the study⁶ ? Yes No NA

Are reporting procedures and management strategies described in the study? Yes No

If Yes, Specify

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7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes No

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⁵For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1

⁶The term adverse events in this regard encompass both serious and non-serious adverse events.

- (b) Version number and date of Participant Information Sheet (PIS):.....
 Version number and date of Informed Consent Form (ICF):.....
- (c) Type of consent planned for :
- | | | | | | | | |
|--|--------------------------|--|--------------------------|---|--------------------------|---|--------------------------|
| Signed consent | <input type="checkbox"/> | Verbal/Oral consent | <input type="checkbox"/> | Witnessed consent | <input type="checkbox"/> | Audio-Video (AV) consent | <input type="checkbox"/> |
| Consent from LAR
(If so, specify from whom) | <input type="checkbox"/> | For children<7 yrs
parental/LAR consent | <input type="checkbox"/> | Verbal assent from
minor (7-12 yrs) along
with parental consent | <input type="checkbox"/> | Written assent from
minor (13-18 yrs) along
with parental consent | <input type="checkbox"/> |
| Other | <input type="checkbox"/> | (specify) | | | | | |
- (d) Who will obtain the informed consent?
- PI/Co-I Nurse/Counselor Research Staff Other (Specify)
- Any tools to be used
- (e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)
- English Local language Other (Specify).....
- List the languages in which translations were done
- If translation has not been done, please justify
- (f) Provide details of consent requirements for previously stored samples if used in the study⁷
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- (g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)
- | | | | | | |
|-------------------------------|--------------------------|----------------------------|--------------------------|--|--------------------------|
| Simple language | <input type="checkbox"/> | Data/ Sample sharing | <input type="checkbox"/> | Compensation for study related injury | <input type="checkbox"/> |
| Risks and discomforts | <input type="checkbox"/> | Need to recontact | <input type="checkbox"/> | Statement that consent is voluntary | <input type="checkbox"/> |
| Alternatives to participation | <input type="checkbox"/> | Confidentiality | <input type="checkbox"/> | Commercialization/ Benefit sharing | <input type="checkbox"/> |
| Right to withdraw | <input type="checkbox"/> | Storage of samples | <input type="checkbox"/> | Statement that study involves research | <input type="checkbox"/> |
| Benefits | <input type="checkbox"/> | Return of research results | <input type="checkbox"/> | Use of photographs/ Identifying data | <input type="checkbox"/> |
| Purpose and procedure | <input type="checkbox"/> | Payment for participation | <input type="checkbox"/> | Contact information of PI and Member | <input type="checkbox"/> |
| Others(Specify) | <input type="checkbox"/> | Secretary of EC | | | |
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8. PAYMENT/COMPENSATION

- (a) Who will bear the costs related to participation and procedures⁸ ?
- PI Institution Sponsor Other agencies (specify)
- (b) Is there a provision for free treatment of research related injuries? Yes No N/A
- If yes, then who will provide the treatment?
- (c) Is there a provision for compensation of research related SAE? If yes, specify. Yes No N/A
- Sponsor Institutional/Corpus fund Project grant Insurance
- (d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes No N/A
- (e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes No N/A

⁷Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.

⁸Enclose undertaking from PI confirming the same

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes No NA

Anonymous/Unidentified Anonymized: Reversibly coded Irreversibly coded Identifiable

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

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(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed⁹ and by whom?

(d) For how long will the data be stored?

(e) Do you propose to use stored samples/data in future studies? Yes No Maybe

If yes, explain how you might use stored material/data in the future?

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SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes No NA

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(b) Will you inform participants about the results of the study? Yes No NA

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes No NA

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.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes No NA

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(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes No NA

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.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes No

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.....

⁹For example, a data entry room, a protected computer etc.

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)

<input type="checkbox"/>	I/We certify that the information provided in this application is complete and correct.
<input type="checkbox"/>	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.
<input type="checkbox"/>	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
<input type="checkbox"/>	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
<input type="checkbox"/>	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
<input type="checkbox"/>	I/We declare that the expenditure in case of injury related to the study will be taken care of.
<input type="checkbox"/>	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
<input type="checkbox"/>	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
<input type="checkbox"/>	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
<input type="checkbox"/>	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
<input type="checkbox"/>	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
<input type="checkbox"/>	I/We have the following conflict of interest (PI/Co-I): 1. 2.
<input type="checkbox"/>	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI:

Signature: dd mm yy

Name of Co-PI:

Signature: dd mm yy

Name of Guide:

Signature: dd mm yy

Name of HOD:

Signature: dd mm yy

¹⁰These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements
 Acknowledgement for Receipt of Application (Copy to be provided to PI)

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4	Approval of scientific committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5	EC clearance of other centers*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6	Agreement between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7	MTA between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PROPOSAL RELATED						
12	Copy of the detailed protocol ¹¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
16	Performa/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PERMISSION FROM GOVERNING AUTHORITIES						
	Other permissions	Required	Not required	Received	Applied dd/mm/yy	EC Remarks
18	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
19	DCGI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
20	HMSC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
21	NAC-SCRT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
22	ICSCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
23	RCGM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
24	GEAC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
25	BARC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
26	Tribal Board	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
27	Others (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	YES	NO	NA	Enclosure no.	EC remarks
28		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
29		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

*For multicentre research.

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

¹¹Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

1.	Signature of PG Student
2.	2a. Remarks, Name and signature of Guide
3.	2b. Remarks, Name of and signature of Co-Guide
4.	Remarks, Name and signature if Head of Department
5.	Name and Signature of Head of Institution