Application Form for Exemption from Review

Central Ethics Committee (CEC)

Nitte (Deemed to be University)

Title of study:
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1. Details of Investigators:

Name	*Designation and Qualification*	*Department and Institution*	*Address for communication²*
Principal Investigator/Guide			
Co-investigator/student/fellow			

(i) Number of studies where applicant is a:
ii) Principal Investigator at time of submission *iii) Co-Investigator at time of submission:*

....

(iv) Duration of the study: .....

2. Choose reasons why exemption from ethics review is requested?

1	Research poses less than minimal risk	☐
2	Research on data in the public domain/ systematic reviews or meta-analyses	☐
3	Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person	☐
4	Quality control and quality assurance audits in the institution	☐
5	Comparison among instructional techniques, curricula, or classroom management methods	☐
6	Consumer acceptance studies related to taste and food quality	☐
7	Public health programmes by government agencies[15]	☐

Any other (please specify in 100 words): .....

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3. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ *Institutional funding* ☐ *funding agency (Specify)* ☐

4. OVERVIEW OF RESEARCH

(a) Laysummary[3] (within 300 words): .....

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b) Type of study:

Basic Sciences	☐	*Clinical*	☐	*Cross Sectional*	☐
Retrospective	☐	*Epidemiological/*	☐	*Case Control*	☐
Prospective	☐	*Public Health*	☐	*Cohort*	☐
Qualitative	☐	*Socio-behavioral*	☐	*Systematic Review*	☐
Quantitative	☐	*Biological samples/ Data*	☐		
Mixed Method	☐	*Any others (Specify)*	☐		

c) Sample size

At site..... In India..... Globally .....

Justification for the sample size chosen _____

d) Is there an external laboratory/outsourcing involved for investigations? *Yes* ☐ *No* ☐ *NA* ☐

5. STORAGE AND CONFIDENTIALITY

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

Anonymous/Unidentified ☐ Anonymised: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

(b) If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data issafeguarded?

(e.g. data stored in a cabinet, password protected computer etc.) .....

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

(d) Where will the data be analyzed[9] and by whom? .....

(e) For how long will the data be stored? .....

(f) 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?.....

SECTION E: DECLARATION AND CHECKLIST [10]

6. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	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 guide- lines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and itsRules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions wherethis study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	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.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict ofinterest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: .....

Signature: .....

Name of Co-PI: .....

Signature: .....

dd	mm	yy
.....	...	

Name of Guide (For Ph. D Students only) :-----

Signature: .....

7. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externallyoutsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
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	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[‡]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biological/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed ConsentForm (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Pro-forma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English andtranslated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

	PERMISSION FROM GOVERNING AUTHORITIES					
	Other permissions	**Required**	**Not required**	**Received**	**Applied dd/ mm/yy**	**EC Remarks**
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

	ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY					
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28		☐	☐	☐		
29		☐	☐	☐		

*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

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