TRANSLATIONAL HEALTH SCIENCES AND TECHNOLOGY INSTITUTE (THSTI)

Four hard copies of the research proposal along with a covering letter and a 'soft copy' on CD are required to be submitted to the

Member Secretary
Institutional Ethics Committee (Human Research)
Translational Health Science and Technology Institute (THSTI)
NCR Biotech Science Cluster, 3rd milestone, Faridabad-Gurgaon Expressway, Faridabad-121001

All Proposals that is submitted to the Ethics Committee should have an investigator from THSTI. **The proposal must be forwarded through the Head of Centre/Institute,** and should be accompanied by the case recording forms/questionnaire and the Informed Consent and Patient Information Sheet in the prescribed format in both English and local language(s). Patient Information sheet should begin with the study title, listing of the Institutions, Principal and Co-Investigators of the study. Institutional Biosafety committee approval should be provided for proposals involving laboratory participation from the THSTI investigators.

Project submission time: Submissions will be received on all working days for initial review by the secretariat. The completed proposals submission received by 15th of each month will be taken up for discussion in the immediate meeting.

Amendment submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and reasons for these amendments.

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FORMAT FOR SUMMARY OF PROPOSAL

(To accompany every proposal submitted to the Institutional Ethics Committee (Human Research))

Reference No. (To be given by the Secretariat) _____

Title of the Proposal _____

_____

_____

1. Information on investigators

Principal Investigator (PI)			**Signature**	**No. of on-going projects with Investigator as a PI**
	Name			
	Designation			
	Affiliation			
	Address			
	Telephone No.			
	Fax No.			
	Email			
Co-Principal Investigator (Co-PI)				
1.	Name			
	Designation			
	Affiliation			
	Address			
	Telephone No.			
	Fax No.			
	Email			
2.	Name			
	Designation			
	Affiliation			
	Address			
	Telephone No.			
	Fax No.			
	Email			
Co-investigators				
1.	Name			
	Designation			
	Affiliation			
	Address			
	Telephone No.			
	Fax No.			
	Email			
2	Name			
	Designation			
	Affiliation			
	Address			
	Telephone No.			

	Fax No.			
	Email			

2. Sponsor(s) Information (If funding of project approved give documentary evidence)

Intramural ☐			
Extramural ☐			
○ Indian ☐	Government ☐	Central ☐	
		State ☐	
		Institutional ☐	
	Private ☐	Industry ☐	
		○ National ☐	
		○ International ☐	
		Agency ☐	
○ International ☐	UN agencies ☐	Other agency ☐	
	Industry ☐	Collaborator ☐	
Name of sponsor(s)			
Contact Address(es)			
Total budget			

3. Study details

A. Type of Study	Epidemiological ☐ Clinical ☐ Behavioral ☐	Basic Sciences involving human subjects ☐ Animal studies ☐
B. Centers	Single center ☐	Multicentric ☐
C. Status of Review	New ☐	Revised ☐
D. Clinical Trial	Yes ☐	No ☐
If yes		
Does the study involve use of	Drug ☐ Device ☐ Vaccine ☐	Indian Systems of Medicine ☐ Alternate System of Medicine ☐ Any other ☐
	If other, specify _____ DCG(I) approval Yes No Submitted	

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Is it approved and marketed	In India ☐		USA ☐	
	UK & Europe ☐		Other countries, specify ☐	
	Specify _____			
If marketed, Does it involve a change in use, dosage, route of administration			Yes ☐	No ☐
If yes, whether the permission of DCGI or any other regulatory authority is obtained for the change in use, dosage, route of administration?			Yes ☐	No ☐
If yes, date of permission: _____			Submitted ☐	
Is it an Investigational New Drug?			Yes ☐	No ☐
If yes, IND No: _____				
Investigator's Brochure submitted			Yes ☐	No ☐
In vitro studies data			Yes ☐	No ☐
Preclinical Studies done			Yes ☐	No ☐
Clinical Study is	Phase I ☐	Phase II ☐	Phase III ☐	Phase IV ☐

E. Brief description of the proposal – Introduction, brief background, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits study subjects inclusion criteria, exclusion criteria, sample size, study design, duration of study, ethical issues in the study and plans to address these issues and outcome measures (Attach sheet with maximum 500 words)

F. Consent Process:		
o Method: Written	Yes ☐	No ☐
o If written consent is not required, give reasons: _____ _____		
o Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐ Research staff ☐ Any other ☐		
G. Privacy and confidentiality		
o Study involves Direct identifiers ☐ Indirect identifiers/coded ☐ Complete anonymity or delinked ☐		
o Confidential handling of data by staff	Yes ☐	No ☐
H. Use of biological/ hazardous materials		

○ Use of fetal tissue or abortus	Yes ☐	No ☐
○ Use of organs or body fluids	Yes ☐	No ☐
○ Use of recombinant/gene therapy	Yes ☐	No ☐
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes ☐	No ☐
○ Use of pre-existing/stored/left over samples	Yes ☐	No ☐
○ Collection for banking/future research ○ **If Yes provide time of storage**	Yes ☐	No ☐
○ Use of ionizing radiation/radioisotopes	Yes ☐	No ☐
If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	Yes ☐	No ☐
○ Use of Infectious/biohazardous specimens	Yes ☐	No ☐
○ Proper disposal of material	Yes ☐	No ☐
I. Will any sample collected from the patients be sent abroad?	Yes ☐	No ☐
○ If Yes, justify with details of collaborators (Enclosure --)		
○ Has the proposal been cleared from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes ☐ Submitted ☐	No ☐
○ Sample will be sent abroad because:		
○ Facility not available in India	Yes ☐	No ☐
○ Facility in India inaccessible	Yes ☐	No ☐
○ Facility available but not being accessed	Yes ☐	No ☐
(If so, reasons)		
J. Is there compensation for participation?	Yes ☐	No ☐
If yes,	Monetary ☐	In kind ☐
Specify amount and type: _____		
K. Is there compensation for injury?	Yes ☐	No ☐
If yes, provided by: Sponsor ☐ Investigator ☐ Insurance ☐ Any other company ☐		
L. Will any advertising or notification be done for recruitment of Subjects?	Yes ☐	No ☐

Comment [N1]: ICMR guidelines say for preparation of gene construct, the guidelines and clearance is regulated by National Bioethics Committee under DBT and for evaluation of efficacy and safety of administered gene, clearance from Central Ethical Committee ICMR is required, pg 69

(Posters, flyers, brochure, websites: if so attach a copy; Enclosure --)		
M. Data Monitoring (for clinical trial)		
o Is it planned to constitute a data and safety monitoring board (DSMB)?	Yes ☐	No ☐
o Is a plan for reporting of adverse events enclosed?	Yes ☐	No ☐
If yes**,** reporting shall be done to: Sponsor ☐ Ethics Committee ☐ DSMB ☐		
o Is there a plan for interim analysis of data?	Yes ☐	No ☐
o Are there plans for storage and maintenance of all trial databases?	Yes ☐	No ☐
If yes**,** for how long? _____		
4. Do any of the Investigators have conflict of interest (financial/nonfinancial)?	Yes ☐	No ☐
If yes, specify : _____		
5. Checklist for attached documents: **Enter Not Applicable if it is not required**		
a. Project proposal (4 Copies)		☐
b. Curriculum Vitae of Investigators		☐
c. Patient information sheet (English and local language)		☐
d. Informed Consent form (English and local language)		☐
e. Investigator's brochure		☐
f. Copy of advertisements/Information brochures		☐
g. Copy of clinical trial protocol		☐
h. Copy of Questionnaire		
i. Institutional Animal Ethics Committee clearance if obtained		☐
j. HMSC/DCGI/DBT/BARC clearance if obtained		☐
k. Declaration by Investigators that recruitment for the study has not been started		☐
l. Undertaking for translation to local language		☐

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Place:
Date: **Signature & Designation of PI / Co-PI / Collaborator**