Form to be filled by the Principal Investigator (PI) for submission to Clinical Research Ethics Committee (CREC), NSMCH

(For attachment to each copy of the proposal)

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐

b) Private ☐

Serial No of CREC, Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email 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).			

2. International Government ☐ Private ☐ UN agencies ☐
3. International Government ☐

Tick appropriately

1.Type of Study : Cross sectional case control cohort Clinical Trial Review Participating Centre : Single center 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? **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission :	Yes Yes	No 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 Yes No
(Tick the appropriate boxes)

captives	institutionalized	employees
students	nurses/dependent	armed
any other	staff	forces

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. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad?	Yes	No
If Yes, justify with details of collaborators		
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 available in India ☐
Facility in India inaccessible ☐
Facility available 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 obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, 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?	Yes	No

If Yes, Minimal or no risk ☐
More than minimum risk ☐
High risk ☐

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? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. 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		

Checklist for attached documents:

Covering letter, through proper channel.	☐
Project proposal – 03 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Ethics Committee clearance	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	☐
In case of multi-centric study, IEC clearance of other centres must be provided	☐
Definite undertaking as to who will bear the expenditure of injury related to the project	☐
In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	☐
Permission to use copyrighted Questionnaire/proforma	☐
Investigator should provide undertaking what they will do with the leftover sample tissue	☐
Certificate/undertaking as mentioned in column 17	☐
Others	☐