Annexure 1-B

AX 1-B/SOP 05/V5

Project submission application form for initial review

for all academic (non-sponsored) studies.

Please fill in the details in legible hand writing

Tick √ in the box for the appropriate answer/ Write NA if question is not applicable

IEC Protocol no. _____

Title of the project

_____
_____
_____
_____
_____

	Name	Designation	Department and Institution
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			
"Principal investigator must be a faculty / employee of Seth G. S. Medical College and KEM Hospital and have appropriate post graduate qualification approved by respective statutory council".			

If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.

Non-sponsored study ☐ **Sponsored study** ☐

If Non-Sponsored Study:

Type of study : Thesis/dissertation ☐ ICMR/KVPY ☐ Other Academic ☐

Duration of study _____ Approx. Completion date (MM/YY) _____

If sponsored,

Total Budget : Rs._____

From where is the study being funded

a) Research fund is being utilized from DJST ☐ Research Society ☐ MRU ☐

Others ☐

If any other, please give details _____

1.Type of Study : Prospective ☐ Retrospective ☐ Cross-sectional ☐

Is the study observational/ Interventional? _____

If interventional, does the study involve any deviation from routine/standard practices?

_____

2. Does the study involve use of : Drug / Vaccine ☐ Device ☐ Alternative Medicine ☐

New Technique (surgical/PT/OT, etc) ☐ Diagnostic Kit/ Investigations ☐

If other, please specify

_____

i) Is the test drug / device marketed in India Yes ☐ No ☐

ii) Does the test drug involve a change in use, dosage, route of administration?

Yes ☐ No ☐

If yes, data generated intended for submission to licensing authority

Yes ☐ No ☐

If yes, please attach copy of DCGI permission.

If no, please attach copy of package insert/product insert.

3. Subject selection:

i) Number of subjects at this centre ☐ if multicentric, total number of subjects ☐

ii) Vulnerable subjects Yes ☐ No ☐ (If yes, tick the appropriate boxes) **(Please refer SOP no 20/v5)**

pregnant women ☐ illiterate ☐ seriously/terminally ill ☐

children ☐ neonates ☐ mentally challenged ☐

elderly ☐ handicapped ☐ economically/socially backward ☐

institutional employees / students ☐ any other ☐

If other, please specify _____

Relevant annexures filled Yes ☐ No ☐

4. Does the study involve use of i) fetal tissue or abortus	Yes ☐	No ☐
ii) organs or body fluids	Yes ☐	No ☐

iii) Gene therapy If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes ☐	No ☐
iv) ionizing radiation/radioisotopes If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission	Yes ☐	No ☐
v) infectious / biohazardous specimens	Yes ☐	No ☐
vi) Will pre-existing/stored/left over samples be used?	Yes ☐	No ☐
vii) Will samples be collected for banking/future research	Yes ☐	No ☐
viii) Will any sample collected from patient be sent abroad? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes ☐	No ☐
ix) Is there any collaboration with any foreign lab., clinic or hospital ? If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.	Yes ☐	No ☐
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IEC review.	Yes ☐	No ☐
6. Is there compensation for participation (traveling allowance)? If Yes, Monetary ☐ In kind ☐ Specify amount / type: _____	Yes ☐	No ☐
7. Are there any arrangements for compensation / treatment of trial related injury? If yes , by sponsor ☐ by investigator ☐ By insurance company ☐ by others ☐ Please submit a copy of the insurance policy if it is available.	Yes ☐	No ☐

8. Do you have any conflict of interest in the present study?

(financial / non – financial/ any other)

If yes, specify: ……

9. Is any other department involved in participant recruitment/investigation, but not co-investigators or collaborators ? Yes/No

If yes, specify ……..

Name and signature of concerned HOD ……

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of Principal Investigator: _____

Signatures of Co- investigators: 1._____ 2._____

3._____ 4. _____

Forwarded by Heads of Department(s) _____ _____

Stamp/Seal of the Department(s)

Please fill the form in legible handwriting or type the information.

Write 'Not Applicable' (NA) wherever necessary.

Incompletely filled form will not be accepted.