Annexure 3C

Application form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal)

S. No. of IEC-IUST Secretarial Office:

Proposal Title:

	Name, Designation, & Qualification(s)	Official Address Tel & Fax Nos. Email ID	No. of years of Research Experience	Signature
PI				
Applicant (In case the applicant is not the PI)				
Co-PI / Collaborators **1.**				
2.				
3.				
Please attach detailed Biosketch of all Investigators (with subject specific publications limited to previous 5 years).				

Tick ☑ appropriately

Islamic University of Science and Technology
Approved Under 12(b) & 2(f) of UGC Act 1956
Institutional Ethics Committee
SOPs

Sponsor Information:

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

b) Private ☐

c) None ☐

2. International ☐ Government ☐ Private ☐ UN agencies ☐

3. Industry ☐ National ☐ Multinational ☐

Contact Address of Sponsor (if applicable)**:**

Total Budget in Approximate:

1.Type of Study: Epidemiological ☐ Basic Sciences Human studies ☐

Animal study ☐ Clinical: Single center ☐ Metacentric ☐ Behavioral ☐

2. Status of Review: New ☐ Modified Revised.

3. Clinical Trials:

Drug /Vaccines/Device/Herbal Remedies:

i. Does the study involve use of :

Drug/chemotherapy ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine Cell model development NA ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ US ☐ Other countries, specify

	☐	☐

iii Does it involve 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):		

ii	Duration of study in months:		
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 ☐ known ethnic group ☐ any other		
iv.	Special group subjects Yes ☐ No ☐ (Tick the appropriate boxes) Captives ☐ Institutionalized ☐ Employees ☐ Students ☐ Nurses/Dependents ☐ Armed Forces ☐ Any Other staff ☐		
6. Privacy and confidentiality i.	Study involves - Direct Identifiers ☐		

Indirect Identifiers/coded Completely anonymized/ delinked		
ii. Confidential handling of data by staff	Yes ☐	No ☐
7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes ☐	No ☐
ii. Use of organs or body fluids	Yes ☐	No ☐
iii. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained.	Yes ☐ Yes ☐	No ☐ No ☐
iv. Use of pre-existing/stored/left over samples	Yes ☐	No ☐
v. Collection for banking/future research	yes ☐	No ☐
Use of ionising radiation/radioisotopes If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes ☐ Yes. ☐	No ☐ No ☐
vii. Use of Infectious/biohazardous specimens	Yes ☐	No ☐
viii. Proper disposal of material	Yes ☐	No ☐
ix. Will any sample collected from the patients be sent abroad ? **If Yes, justify with details of collaborators**	Yes ☐	No ☐
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 ☐

Confidentiality of records ☐

Statement that study involves research ☐

Purpose and procedures ☐

Risks & Discomforts ☐

Right to withdraw ☐

Statement that consent is voluntary ☐

Benefits if any on future

Compensation for participation ☐

Consent for future use of biological material for commercialization.

eg. (i) genetic basis for drug development ☐

(ii) Cell model development ☐

Compensation for study related injury ☐

*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? **If Yes,** Minimal or no risk More than minimum risk High risk	Yes ☐	No ☐
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 ☐ **3 years**	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 ☐

Checklist for attached documents:

Project proposal –10 Copies……

Curriculum Vitae of Investigators……

Brief description of proposal……

Patient information sheet……

Informed Consent form……

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 obtained……

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Place:
Date:

Signature & Designation of Head of the Department
(not required in case the Principal investigator is a Professor)