

> **SOPs** DCGI Registration No:ECR/1535/Inst/JK/2021 DHR Registration No: under process

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)

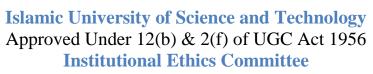
S. No. of IEC-IUST Secretarial Office:

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.				
<u>2.</u> 3.				

Please attach detailed Biosketch of all Investigators (with subject specific publications limited to previous 5 years).

Tick ☑ appropriately



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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



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iii Does it involve change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory	Yes	No.
authority's		
Permission is obtained.		
If yes, Date of permission:		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND 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 li	terature, aim(s)	& objectives,
justification for study, methodology describing the potential risks	& benefits, out	come measures,
statistical analysis and whether it is of national significance with maximum 500 words):	rationale (Attach	n sheet with



ii Durati	ion 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 subjectsYesNo(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 an	d confidentiality
i.	Study involves - Direct Identifiers



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Indirect Identifiers/co	oded	
Completely	anonymized/	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
Use of ionising radiation/radioisotopes		
If yes, has Bhaba Atomic Research Centre (BARC) approval	Yes Yes	No No
for Radioactive Isotopes been obtained?		
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



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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 b) Benefit to society	Indirect	
11. Data Monitoringi) 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,MonetaryIn kindSpecify amount and type:	Yes	No
13. Is there compensation for injury?If Yes, by Sponsorby Investigatorby insurance companyby any other	Yes	No



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Yes	No	
Curriculum Vitae of Investigators		
Brief description of proposal		
Patient information sheet		
Copy of clinical trial protocol and/or questionnaire		
Institutional Ethics Committee clearance		

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)