OFFICE OF THE DEAN & PRINCIPAL
FAKIR MOHAN MEDICAL COLLEGE & HOSPITAL, BALASORE
(Formerly known as Government Medical College & Hospital, Balasore)
At/Po/Dist.- Balasore, Pin- 756019 (Odisha)
E-mail: dean.gmchb@gmail.com , Tel 06782 – 224901, Fax: 06782 – 224901

No. 1286 /D/FMMCHB Date: 20.04.22

N O T I C E

The Institutional Ethics Committee meeting shall be held on the 3rd week of May 2022. In this regard, the interested students, Residents, Faculty Members are informed to submit their research proposal in proper format in the Office of the undersigned by 4 P.M. of 05.05.2022. Late submission of the proposal shall not be accepted. The IEC form is available in the website www.blsmch.nic.in

20.04.22

Dean & Principal,
Fakir Mohan Medical College & Hospital, Balasore.

Dean & Principal
Fakir Mohan Medical College
& Hospital, Balasore.

Memo No. 1287 /D/FMMCHB Date: 20.04.22

Copy forwarded to the Chairperson, Institutional Ethics Committee, FMMCH, Balasore for information. You are requested to make it convenient to attend the meeting.

Copy forwarded to all the members of Institutional Ethics Committee, FMMCH, Balasore for information & necessary action.

Copy to the Notice Board/ website for wide circulation.

20.04.22

Dean & Principal,
Fakir Mohan Medical College & Hospital, Balasore.

Dean & Principal
Fakir Mohan Medical College
& Hospital, Balasore.

Institutional Ethics Committee, Fakir Mohan Medical College & Hospital, Balasore

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

(Prepared with reference to ICMR Format)

Proposal Title:

	Name, Designation & Qualifications	Address Tel & Fax Nos. E mail ID	Signature
PI			
Co-PI/ Collaborator 1.			
2.			
3.			
Please attach detailed curriculum Vita of all investigators (With subject specific publications to previous 5 years)			

Tick appropriately

Sponsor Information: 1. Indian	a) Government	☐	Central ☐	State ☐	Institutional ☐		
	b) Private	☐					
2. International	Government	☐	Private	☐	Others	☐	
3. Industry	National	☐	Multinational	☐			
Contact address of the sponsor:							
Total Budget:							

I.E.C., Fakir Mohan Medical College & Hospital, Balasore

1. Type of Study:	Clinical ☐		Epidemiological ☐	
	Behavioral ☐			
	Other ☐			
		Specify		
Whether :	Multicentric ☐	☐		
	Single Center ☐			
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 ☐	Any Other ☐	NA ☐	
	Alternate System of Medicine			
ii. Is it approved and marketed				
	In India ☐	& Europe ☐	USA ☐	
	Other countries, Specify ☐			
iii. Does it involve a Change in use, dosage, route of administration?			Yes	No
If yes, Whether DGCI's/ Any other Regulatory authority's permission is obtained?			Yes	No
If yes, Date of Permission:				
iv. Is it an investigational New Drug? If yes, IND No:			Yes	No
a) Investigational Brochure Submitted				
b) In vitro studies data				
c) Preclinical Studies done				
d) Clinical Study is:	Phase I ☐	Phase II ☐	Phase III ☐	Phase IV ☐
e) Are you aware if this study/similar study is being done elsewhere? If yes, attach details			Yes	No

I.E.C., Fakir Mohan Medical College & Hospital, Balasore

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 & 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: Volunteer ☐ Patients ☐

vi. Vulnerable subjects Yes No

(Tick the appropriate boxes)

Pregnant Women	☐	Children	☐	Iderly	☐
Fetus	☐	Illiterate	☐	Handicapped	☐
Terminally ill	☐	Seriously ill	☐	Mentally Challenged	☐
Economically & Socially backward	☐	Any other	☐		

Special group subjects Yes No

(Tick the appropriate boxes)

Captives	☐	Institutionalized	☐	Employees	☐
Students	☐	Nurses/Dependent	☐	Armed forces	☐
Any other	☐	Staff	☐		

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 i. Use of fetal tissue or abortus	Yes	No
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 DNA 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/radioisotopes	Yes	No
if yes, Has Bhaba Atomic Research Center(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 patient be sent abroad? If yes, justify with details of collaborators	Yes	No
a) Is the proposal being submitted for clearance from Health Minister's screening committee (HMSE) for International collaboration?	Yes	No

b) Sample will be sent to 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	☐	Ulternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedure	☐	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/Counselor ☐
Research staff ☐ Any other ☐

9. Will any advertising be done for requirement of subjects? Yes No
(Posters, flyers, Brochure, websites- if so kindly attach a copy)

10. Risk & benefits:
i. Is the risk reasonable compared to the anticipated benefits? Yes No
to subject/ community/ Country?

ii. Is there physical/social/psychological risk/discomfit? Yes No
If yes, Minimal or no risk ☐
More than minimum risk ☐
High Risk ☐

iii. Is there any 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 an adverse event? If Yes, reporting is done to Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
iv. Are there plans for storage & maintenance of all trial database? If Yes, How long?	Yes	No
12. Is there compensation for participation? If yes, Monetary ☐ In kind ☐ Specify amount & 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/non-financial) If yes, specify	Yes	No

Checklist for document attached

- Project proposal – 12 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 ☐
- HMSC/DCGI/DBT/BARC clearance if obtained ☐

Signature of Co-PI/
Collaborator

Signature & Designation of PI

Place:
Date:

THE BASIC PRINCIPLE TO BE FOLLOWED BY THE IEC IS -

No one shall be subjected to torture or to cruel inhumane or degrading treatment or punishment. In particular no one shall be subjected without his consent to medical or scientific treatment (International Convenant on Civil & Political Rights).

REVIEW PROCEDURES OF THE IEC

1. The IEC will review every research proposal on human subjects after the research proposal is being thoroughly scientifically evaluated.

The researcher who will submit the application in proper protocol for biomedical research in human subjects should attach a certificate of scientific evaluation of the essentiality of this research work at least from two senior teachers in or above the rank of assistant professors who have worked and have adequate knowledge in that particular field but are not directly involved in the present study.

THE PROFORMA OF THE CERTIFICATE OF SCIENTIFIC EVALUATION

I / We, after thorough scientific evaluation of the relevant and authentic documents available on this field both from human and or animal research studies reached in a conclusion that this research work entitled :

is scientifically valid and essential for the benefit of the treatment of patients.

No serious or life threatening adverse effect has been reported in literatures by use of this new drug / drug combinations /or/ the procedures under study in this particular condition except in rare instances.

So I / We recommend this research proposal to the IEC for necessary approval.

Signature-	Signature-
Name-	Name-
Seal-	Seal-

Forwarded through the Head of the Department

HOD
Seal