



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)



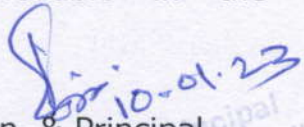
E-mail: dean.fmmchb@gmail.com , Tel 06782 - 224901, Fax: 06782 - 224901

No. 135 /D/FMMCHB

Date: 10.01.23

N O T I C E

The Institutional Ethics Committee meeting shall be held on the month of February-2023. Research Proposals are invited from interested Students, Residents and Faculty members to be submitted in the office of the undersigned by 4 P.M. of 04.02.2023. Late submission of research proposals shall not be accepted. The IEC form is available in the website (www.blsmch.nic.in).


Date: 10.01.23
Dean & Principal,

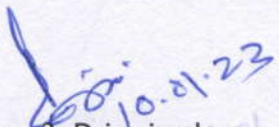
Fakir Mohan Medical College & Hospital, Balasore.

Memo No. 136 /D/FMMCHB

Date: 10.01.23

Copy forwarded to the Chairperson, Institutional Ethics Committee, FMMCH, Balasore for information.

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

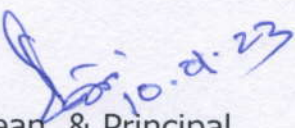

Date: 10.01.23
Dean & Principal,

Fakir Mohan Medical College & Hospital, Balasore.

Memo No. 137 /D/FMMCHB

Date: 10.01.23

Copy forwarded to the Superintendent/ All HODs, FMMCH, Balasore for information & necessary action.


Date: 10.01.23
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	<input type="checkbox"/>	Central <input type="checkbox"/> State <input type="checkbox"/> Institutional <input type="checkbox"/>
	b) Private	<input type="checkbox"/>	
2. International	Government	<input type="checkbox"/>	Private <input type="checkbox"/> Others <input type="checkbox"/>
3. Industry	National	<input type="checkbox"/>	Multinational <input type="checkbox"/>
Contact address of the sponsor:			
Total Budget:			

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

1. Type of Study:		Clinical <input type="checkbox"/>	Epidemiological <input type="checkbox"/>
		Behavioral <input type="checkbox"/>	
		Other <input type="checkbox"/>	
		Specify	
Whether :	Multicentric <input type="checkbox"/>	<input type="checkbox"/>	
	Single Center <input type="checkbox"/>		
2. Status of Review:		New <input type="checkbox"/>	Revised <input type="checkbox"/>
3. Clinical Trials:			
Drug/ vaccines/Device/ Herbal Remedies:			
i. Does the study involve use of:			
	Drug <input type="checkbox"/>	Devices <input type="checkbox"/>	Vaccines <input type="checkbox"/>
	Indian Systems of Medicine <input type="checkbox"/>	Any Other <input type="checkbox"/>	NA <input type="checkbox"/>
	Alternate System of Medicine		
ii. Is it approved and marketed			
	In India <input type="checkbox"/>	& Europe <input type="checkbox"/>	USA <input type="checkbox"/>
	Other countries, Specify <input type="checkbox"/>		
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?		Yes	No
If yes, IND No:			
a) Investigational Brochure Submitted			
b) In vitro studies data			
c) Preclinical Studies done			
d) Clinical Study is:		Phase I <input type="checkbox"/>	Phase II <input type="checkbox"/>
		Phase III <input type="checkbox"/>	Phase IV <input type="checkbox"/>
e) Are you aware if this study/similar study is being done elsewhere?		Yes	No
If yes, attach details			

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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 <input type="checkbox"/>	Patients <input type="checkbox"/>
vi. Vulnerable subjects	Yes	No
(Tick the appropriate boxes)		
Pregnant Women <input type="checkbox"/>	Children <input type="checkbox"/>	Elderly <input type="checkbox"/>
Fetus <input type="checkbox"/>	Illiterate <input type="checkbox"/>	Handicapped <input type="checkbox"/>
Terminally ill <input type="checkbox"/>	Seriously ill <input type="checkbox"/>	Mentally Challenged <input type="checkbox"/>
Economically & Socially backward <input type="checkbox"/>	Any other <input type="checkbox"/>	
Special group subjects	Yes	No
(Tick the appropriate boxes)		
Captives <input type="checkbox"/>	Institutionalized <input type="checkbox"/>	Employees <input type="checkbox"/>
Students <input type="checkbox"/>	Nurses/Dependent <input type="checkbox"/>	Armed forces <input type="checkbox"/>
Any other <input type="checkbox"/>	Staff <input type="checkbox"/>	
6. Privacy and Confidentiality		
i. Study involves-	Direct identifiers	<input type="checkbox"/>
	Indirect identifiers/Coded	<input type="checkbox"/>
	Completely anonymised/ delinked	<input type="checkbox"/>
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

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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 <input type="checkbox"/> Oral <input type="checkbox"/> Audio-visual <input type="checkbox"/>		
i. Consent form: (tick the included elements)		
Understandable language	<input type="checkbox"/>	Alternatives to participation <input type="checkbox"/>
Statement that study involves research	<input type="checkbox"/>	Confidentiality of records <input type="checkbox"/>
Sponsor of study	<input type="checkbox"/>	Contact information <input type="checkbox"/>
Purpose and procedure	<input type="checkbox"/>	Statement that consent is voluntary <input type="checkbox"/>
Risks & Discomforts	<input type="checkbox"/>	Right to withdraw <input type="checkbox"/>
Benefits	<input type="checkbox"/>	Consent for future use of Biological material <input type="checkbox"/>
Compensation for participation	<input type="checkbox"/>	Benefits if any on future commercialization <input type="checkbox"/>
Compensation for study related injury	<input type="checkbox"/>	(eg. Genetic basis for drug development) <input type="checkbox"/>
* If written consent is not obtained, give reasons:		
ii. Who will obtain consent?	PI/Co-PI <input type="checkbox"/>	Nurse/Counselor <input type="checkbox"/>
	Research staff <input type="checkbox"/>	Any other <input type="checkbox"/>
9. Will any advertising be done for requirement of subjects? (Posters, flyers, Brochure, websites- if so kindly attach a copy)	Yes	No
10. Risk & benefits:		
i. Is the risk reasonable compared to the anticipated benefits? to subject/ community/ Country?	Yes	No
ii. Is there physical/social/psychological risk/discomfit?	Yes	No
If yes, Minimal or no risk	<input type="checkbox"/>	
More than minimum risk	<input type="checkbox"/>	
High Risk	<input type="checkbox"/>	
iii. Is there any benefit a) to the subject?		
Direct	<input type="checkbox"/>	Indirect <input type="checkbox"/>
b) Benefit to society	<input type="checkbox"/>	

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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 <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input type="checkbox"/>	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 <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount & type:	Yes	No
13. Is there compensation for injury? If yes, by sponsor <input type="checkbox"/> by investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other <input type="checkbox"/> Company	Yes	No
14. Do you have conflict of interest? (Financial/non-financial) If yes, specify	Yes	No
<p>Checklist for document attached</p> <p>Project proposal – 12 Copies <input type="checkbox"/></p> <p>Curriculum Vitae of Investigators <input type="checkbox"/></p> <p>Brief description of proposal <input type="checkbox"/></p> <p>Patient information sheet <input type="checkbox"/></p> <p>Informed consent form <input type="checkbox"/></p> <p>Investigator’s brochure for recruiting subjects <input type="checkbox"/></p> <p>Copy of advertisements/information brochures <input type="checkbox"/></p> <p>Copy of clinical trial protocol and/or questionnaire <input type="checkbox"/></p> <p>HMSC/DCGI/DBT/BARC clearance if obtained <input type="checkbox"/></p>		

Signature of Co-PI/
Collaborator

Signature & Designation of PI

Place:

Date: