GANGADHAR MEHER UNIVERSITY
AMRUTA VIHAR, SAMBALPUR

NOTICE

No.2022/EC

Date 6/3/2020

The review meeting of Institutional Ethics Committee for Human Research is scheduled on 12.03.2020 at 11.30 A.M. in the conference hall of G.M. University, Sambalpur. All the PhD scholars doing research work involving human participants are invited to present their project proposal / PhD synopsis before the Committee.

Kindly come prepared with 5 power point slides highlighting the ethics components in the protocol of your study and define your proposal. Also submit the following documents to Dr. H.K. Nayak, Member Secretary of IEC on or before 11.03.2020 by 02.00 P.M.

1. Filled in application form
2. Information sheet
3. Consent form
4. Brief description of your proposal in 500 words
5. Questionnaires, if any

Looking forward to meeting you on 12.03.2020.

With best wishes

Registrar
G.M. University, Sambalpur

Memo No.2023/EC

Date 6/3/2020

Copy to PA to VC / P.A. to Registrar / Deputy Registrar / Notice boards / all Supervisors with a request to inform their PhD scholars / System Manager, ICT Cell with a request to put it on the website for information and necessary action.

Registrar
G.M. University, Sambalpur

Registar
Gangadhar Meher University
Sambalpur

APPLICATION FORM

Institutional Ethics Committee (IEC) for Human Research

(To be filled in by the Principal Investigator / Research Scholar for submission to Institutional Ethics Committee)

1. Name, designation and address of Principal Investigator / Research Scholar (Attach a curriculum vitae of PI / RS) :

2. Proposed title of the research work :

3. Brief description of the proposal : (Attach separate sheet with maximum 500 words)

4. Type of study (Tick appropriately) :

Clinical		Single centre	
Behavioral		Multi centric	
Epidemiological		Others	

5. Status of Review :

New		Revised	

6. Clinical Trials :

(i) Does the study involve use of :

Drug		Indian Systems of Medicine/ Alternate System of Medicine	
Devices		Any other	
Vaccines		Not applicable	

(ii) Is it approved and marketed :

In India		USA	
UK & Europe		Other countries, specify	

(iii) Does it involve a change in use, dosage, route of administration? :

Yes		No	

If yes, whether DCGI'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) 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 III	
Phase II		Phase IV	

(e) Are you aware if this study / similar study is being done elsewhere? If Yes, attach details :

Yes		No	

7. Subject selection *(Tick the appropriate boxes)* :

(i) Number of Subjects :

(ii) Duration of study :

(iii) Will subjects from both sexes be required :

Yes		No	

(iv) Inclusion/exclusion criteria given :

Yes		No	

(v) Type of subjects :

Volunteers		Patients	

(vi) Vulnerable subjects :

Yes		No	

Pregnant women		Elderly	
Fetus		Handicapped	
Terminally ill		Mentally challenged	
Children		Economically & socially backward	
Illiterate		Any other	
Seriously ill			

(vii) Special group subjects :

If Yes,

Yes		No	

Captive		Nurses/dependent staff	
Students		Employees	
Any other		Armed forces	
Institutionalized			

8. Consent :

*Written		Oral	
Audio-visual			
* If written consent is not obtained give reasons	:		

(i) Consent form: (Tick the included elements) :

Understandable language	
Statement that study involve research	
Sponsor of study	
Purpose and procedures	
Risks & Discomforts	
Benefits	
Confidentiality of records	
Contact information	
Statement that consent is voluntary	
Right to withdraw	
Consent for future use of biological material	

9. Privacy and confidentiality :

(i) Study involves :

Direct Identifiers	
Indirect Identifiers / coded	
Completely anonymised / delinked	

(ii) Confidential handling of data by staff :

Yes		No	

10. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochure, websites - if so kindly attach a copy) :

Yes		No	

11. 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 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	

(vi) Use of ionizing radiation / radioisotopes :

Yes		No	

If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? :

Yes		No	

(vii) Use of Infectious / bio-hazardous specimens :

Yes		No	

If yes, justify with details of collaborators
(a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaborations?

(viii) Proper disposal of material :

Yes		No	

12. 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? :

Yes		No	

If Yes,

Minimal or no risk	
More than minimum risk	
High risk	

(iii) Is there a benefit

(a) To the subject :

Direct		Indirect	

(b) Benefit to society :

Yes		No	

13. Data Monitoring :

(i) Is there a data & safety monitoring committee / Board? (DSMB)? :

Yes		No	

(ii) Is there a plan for reporting of adverse events? :

Yes		No	

If Yes, reporting is done to :

Sponsor	
Ethics Committee	
DSMB	

(iii) Is there a plan for interim analysis of data?

Yes		No	

(iv) Are there plans for storage and maintenance of all trial data base? :

Yes		No	

If Yes, for how long

14. Is there compensation for participation? :

Yes		No	

If Yes, :

Monetary		In kind	
Specify amount and type:			

15. Is there compensation for injury? :

Yes		No	

If Yes, :

By sponsor		By Investigator	
By insurance company		By any other	

16. Do you have conflict of interest?

Yes		No	

If Yes, specify:

Financial	
Non-financial	

Place: _____

Date: _____

Signature of Applicant

INFORMATION SHEET

(To be supplied by Principal Investigator)

1.	Name of the Principal investigator / Research scholar	:	
2.	Address	:	
3.	Proposed title of the research work	:	
4.	Voluntary participation	:	
5.	Procedure	:	
6.	Duration	:	
7.	Side effects	:	
8.	Risk	:	
9.	Benefits	:	
10.	Confidentiality	:	
11.	Sharing the result	:	
12.	Right to refuse or withdraw	:	
13.	Whom to contact	:	

Name & designation of Principal Investigator / Research Scholar

Contact No._____

Email ID _____

CONSENT FORM

(To be obtained from participants)

I am willing to participate in the research work carried out by _____

_____

He / they has/have already given me all information about his /their research work entitled _____

_____

My participation in the study is entirely voluntary.

1.	Name of participant	:	
2.	Address	:	
3.	Telephone No.	:	
4.	Email ID, if any	:	

Place _____
Date _____

Signature of the participant

Signature & name of witness
Date _____

Signature & name of the person obtaining consent
Date _____