GANGADHAR MEHER UNIVERSITY
AMRUTA VIHAR, SAMBALPUR

No. 3042 / GMU / EC Date : 23/04/2021

NOTICE

All the research scholars of Ph.D. program doing research work on human beings are requested to apply in prescribed format along with the synopsis or related documents for clearance from the institutional Ethics Committee of this University.

The application should reach to the Controller of Examinations on or before 30.04.2021. The application form is available in the University Website i.e. www.gmuniversity.ac.in.

23/4/21
Controller of Examinations
G.M. University, Sambalpur
Controller of Examinations
G.M. University, Sambalpur

Memo No. 3043 / GMU / EC Date : 23/04/2021

Copy to PA to VC / PA to Registrar / Dy. Registrar / Dean, Rearch / All HoDs with Ph.D. program / System Manager, ICT Cell with a request to upload in University Website for information and necessary action.

23/4/21
Controller of Examinations
G.M. University, Sambalpur
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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

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 _____

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 _____