Pt. RAVISHANKAR SHUKLA UNIVERSITY
RAIPUR, CHHATTISGARH

Letter No. 263 /IEC/PRSU/2017 Raipur, Dated 08.01.2017

INVITATION

For Case Presentation related to human research for Institutional Ethics Committee (IEC) approval.

Last date of submission: **January 24, 2017**

Submit hard copy (8 copies) of IEC during office hours:

School of Regional Studies and Research
Pt. Ravishankar Shukla University
Raipur – 492010 (Chhattisgarh)
Submit Soft copy and Hard copy of -

i. Research Project proposal / Ph.D. Synopsis
ii. Ph.D. Course Work Certificate/ Project Proposal
iii. Curriculum Vitae of Investigators / Research Scholar
iv. Brief description of proposal (500 words)
v. Patient information sheet
vi. Informed Consent form
vii. Copy of clinical trial protocol and/or questionnaire

Soft copy should be submitted by email ID: **iec.rsu@gmail.com**

Date: 08.01.2017

Member-Secretary
IEC for Human Research

MEMBER SECRETARY
IEC, HUMAN RESEARCH
PRSU, RAIPUR

Enclosure:

ii) Model form to be filled by the Principal Investigator (PI)/Research Scholar for submission to Institutional Ethics committee (IEC)

Copy to:

1. SoS in Anthropology
2. SoS in Bioscience, Pt. RSU
3. SoS in Geography
4. SoS in Biotechnology
5. Institute of Management
6. Institute of Teacher Education
7. SoS in Physical Education
8. SoS in Psychology
9. University Institute of Pharmacy
10. NCNR, Pt. RSU
11. School of Regional Studies and Research
12. DCDC with a request to circulate the notification in all affiliated colleges Of PRSU
13. Dy. Registrar, Academic Section, PRSU, Raipur
14. Finance Controller, PRSU, Raipur
15. SoS Computer Science with a request to put it on Web site of PRSU
16. Secretary to the VC, PRSU Raipur for information
17. PA to the Registrar, PRSU Raipur for information

All correspondence should be made through only email: **iec.rsu@gmail.com**

Shri Ramesh

12.1.17

Pt. Ravishankar Shukla University, Raipur (C.G.)

Institutional Ethics Committee (IEC) for Human Research
Pt. Ravishankar Shukla University, Raipur (C.G.)

Model form to be filled by the Principal Investigator (PI)/Research Scholar for submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)

Proposal Title:

	Name, Designation & Qualifications	**Address Tel/Mobile & Fax Nos. Email ID**	**Signature**
PI/ Research Scholar/ Investigator			
Co-PI			
Collaborator/ Advisor			

Tick appropriately

Sponsor Information : 1. Indian a) **Government** ☐ Central ☐ State ☐ Institutional ☐ b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National ☐ Multinational ☐
Contact Address of Sponsor:
Total Budget : Rs.

Pt. Ravishankar Shukla University, Raipur (C.G.)
Institutional Ethics Committee (IEC) for Human Research
Pt. Ravishankar Shukla University, Raipur (C.G.)

1.Type of Study :	Clinical ☐	Epidemiological ☐		
	Behavioral ☐			
	Other ☐	Specify: R & D:		
Whether :	Multicentric ☐	Single center ☐		
2. Status of Review:	New ☐	Revised ☐		
3. Clinical Trials: NA				
Drug /Vaccines/Device/Herbal Remedies :				
i. Does the study involve use of :				
Drug ☐	Devices ☐	Vaccines ☐		
Indian Systems of Medicine/ Alternate System of Medicine ☐	Any other ☐	**NA** ☐		
ii. Is it approved and marketed: NA				
In India ☐	UK & Europe ☐	USA ☐		
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? **If yes,** Date of permission :			YES	NO
iv. Is it an Investigational New Drug? **If yes,** IND No:			YES	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 elsewhere ? **NA** **If Yes**, attach details			YES	NO

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 and 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 — Volunteers ☐ Patients ☐

vi. Vulnerable subjects — Yes ☐ No ☐
(Tick the appropriate boxes)

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

vii. Special group subjects: Yes ☐ No ☐
(Tick the appropriate boxes)

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

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 **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