Pt. RAVISHANKAR SHUKLA UNIVERSITY
RAIPUR, CHHATTISGARH

Letter No. 288 /IEC/PRSU/2017 Raipur, Dated 17.08.2017

INVITATION

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

Last date of submission: **August 25, 2017**

Submit Hard copy of -

i. Ph.D. Synopsis
ii. Research Project proposal
iii. Ph.D. Course Work Proposal
iv. M.A./M.Sc. Dissertation Synopsis
v. Curriculum Vitae of Investigators / Research Scholar
vi. Brief description of proposal (500 words)
vii. Patient information sheet
viii. Informed Consent form (Hindi & English)
ix. Copy of clinical trial protocol and/or questionnaire/Schedule

Note:

- **Candidates apply for the Ph.D. Registration should submit the hard copy (9 copies) to --**
  Dy. Registrar (Academic Section)
  Pt. Ravishankar Shukla University, Raipur-492010
  and soft copy by email: iec.rsu@gmail.com

- **Candidates apply for Research Project, Ph.D. course work and M.Sc. Dissertation should submit the hard copy (9 copies) to –**
  Member Secretary, IEC for Human Research
  School of Regional studies and Research
  Pt. Ravishankar Shukla University, Raipur-492010
- Soft copy should be submitted by email: **iec.rsu@gmail.com**

Member Secretary,
IEC for Human Research

MEMBER SECRETARY
IEC, HUMAN RESEARCH
PRSU, RAIPUR

Enclosure:

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

Copy to:

1. Dy. Registrar, Academic Section, PRSU, Raipur
2. DCDC with a request to circulate the notification in all affiliated colleges of PRSU
3. All SoS, PRSU, Raipur
4. University Institute of Pharmacy
5. NCNR, Pt. RSU
6. Finance Controller, PRSU, Raipur
7. SoS Computer Science with a request to put it on Web site of PRSU
8. Secretary to the VC, PRSU Raipur for information
9. PA to the Registrar, PRSU Raipur for information

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

v. Collection for banking/future research	YES	NO
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	YES	NO
vii. Use of Infectious/biohazardous specimens **If Yes, justify with details of collaborators** a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	YES	NO
viii. Proper disposal of material	YES	NO
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	YES	NO
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? b) Sample will be sent abroad because (*Tick appropriate box*)	YES	NO

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 ☐ Alternatives to participation ☐

Statement that study involves research ☐ Confidentiality of records ☐

Sponsor of study ☐ Contact information ☐

Purpose and procedures ☐ 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: In all cases unable to sign due to illiterate.

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐

Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	YES	NO
10. 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? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	YES	NO
iii.Is there a 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 of adverse events ? **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 and maintenance of all trial database? **If Yes,** for how long ?	YES	NO
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and 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/nonfinancial) If Yes, specify :	YES	NO

Checklist for attached documents:

Project proposal – 1 Copy ☐

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 ☐

Place & Date Signature of Applicant