Pt. RAVISHANKAR SHUKLA UNIVERSITY
RAIPUR- 492010, CHHATTISGARH

Letter No. 353 **/IEC/PRSU/2021** **Date: 15.02.2021**

INVITATION

Applications are invited for Case Presentation related to human research for Institutional Ethics Committee (IEC) approval. Only new cases will be discussed in the meeting. The cases will be selected on the first come first serve basis. In case of Ph.D. synopsis, the application will be accepted after DRC approval only.

Last date of submission of application: March 4, 2021

Tentative date of meeting: March 19-20, 2021

Submit hard copy (9 copies) of proposal (PhD synopsis, research project & PG dissertation) along with the following documents:

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

to:

Prof. Arti Parganiha, Member Secretary, IEC for Human Research, School of Studies in Life Science, Pt. Ravishankar Shukla University, Raipur – 492010, Chhattisgarh

Soft copy of all these documents should be submitted to email ID: iec.rsu@gmail.com

Note: Soft copy of the document should be sent in MS Word format and Times New Roman font (font size 12) for English; and Kruti Dev 10 (font size 14) for Hindi.

15.2.2021

Date: 10.02.2021

Member Secretary
MEMBER SECRETARY
IEC, HUMAN RESEARCH
PRSU, RAIPUR

Enclosure:

i) Model application form to be filled by the Principal Investigator (PI)/Research Scholar
ii) Model Consent Form
iii) Model Information Sheet

Copy to:

1. OSD, Academic Section, PRSU, Raipur
2. All Heads, SoS, PRSU, Raipur
3. NCNR, PRSU, Raipur
4. SoS Computer Science with a request to put it on Website of PRSU
5. Finance Controller, PRSU, Raipur
6. Secretary to the VC, PRSU, Raipur for information
7. PA to the Registrar, PRSU, Raipur for information
8. DCDC with a request to circulate the notification in all affiliated colleges of PRSU

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

15.2.2021

Date: 10.02.2021

Member Secretary
MEMBER SECRETARY
IEC, HUMAN RESEARCH
PRSU, RAIPUR

Pt. Ravishankar Shukla University, Raipur

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

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 & 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：

1.Type of Study :	Clinical ☐		Epidemiological ☐	
	Behavioral ☐			
	Other ☐		Specify: R & D:	
Whether :	Multi-centric ☐		Single center ☐	
2. Status of Review:	New ☐		Revised ☐	
3. Clinical Trials:				
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 : **NA** Phase I ☐	Phase II ☐	Phase III ☐	Phase IV ☐	
e). Are you aware if this study/similar study is being done elsewhere? **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 ionizing radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for	YES	NO

Radioactive Isotopes been obtained?		
vii. Use of Infectious/bio-hazardous 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/ Thumb Impression

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 subjects may unable to sign due to illiterate.

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

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 databases? **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

प्रतिभागी का सूचित सहमति–पत्र
[INFORMED CONSENT FORM OF PARTICIPANT]

इस अध्ययन हेतु प्रतिभागी का क्रमांकः .....
शोधकर्ता का नाम व पता

पी–एच.डी./रिसर्च प्रोजेक्ट का शीर्षक : .....

Title of Ph.D./Research Project: .....

पी–एच.डी. रजिस्ट्रेशन नं./रिसर्च प्रोजेक्ट स्वीकृत आदेश क्रमांकः.....
शोध निर्देशक/परियोजना–प्रमुख का नामः.....
संस्था का नाम व पताः.....

सूचना–पत्र में दी गई जानकारियॉ दिनांक .....,को जो दी जा रही है उसे सावधानीपूर्वक मेरे द्वारा पढ़ी गई है/मुझे विस्तार से उस भाषा में समझाया गया है, जो मैं समझता/समझती हूॅ, एवं इसकी विषय–वस्तु को मैं पूर्ण रूप से समझ गया/गयी हूॅ। मै यह पुष्टि करता/करती हूं कि मुझे प्रश्न करने का अवसर दिया गया था।

इस अध्ययन की प्रकृति एवं उद्देश्य तथा इसके संभाव्य जोखिम/लाभों के बारे में एवं अध्ययन के अनुमानित समय के बारे में तथा अध्ययन से संबंधित अन्य जानकारियों के बारे में मुझे विस्तार से समझाया गया है, मै यह समझता/समझती हूॅ कि मेरी भागीदारी स्वैच्छिक है एवं यह कि मै किसी भी समय बिना किसी कारण बताए अध्ययन में भाग न लेने के लिए स्वतंत्र हूॅ। अध्ययन से संबंधित जानकारियों का मेरी निजता/बौद्धिक संपदा/चिकित्सा अथवा कानूनी अधिकार पर प्रभाव नही पड़ेगा।

मै यह समझता/समझती हूॅ कि इस शोध में मेरी भागीदारी से जो मेरे बारे में जानकारियॉ एकत्रित की जा रही है वह पूर्णतः गोपनीय रखी जायेंगी एवं इसका उपयोग अकादमिक कार्य के लिये ही होगा।

मै उपरोक्त अध्ययन में भाग लेने की सहमति देता/देती हूॅ। इसके साथ ही मै अपने फोटो को शोध कार्य हेतु लेने की अनुमति देता/देती हूॅ

दिनांकः .....

(हस्ताक्षर/बाऍ अंगूठे का निशान):..... स्थानः .....

प्रतिभागी का नाम : .....

पिता/पति का नाम : .....

पूर्ण पता : .....

.....

मो. नं.:.....

प्रमाणित किया जाता है कि उपरोक्त सहमति मेरी उपस्थिति में दी गई है।

1) गवाह–1

.....
(हस्ताक्षर)

नाम : .....

पता : .....

2) गवाह–2

.....
(हस्ताक्षर)

नाम : .....

पता : .....

INFORMATION SHEET

1	**Name of the Principal investigators** मुख्य शोधकर्ता का नाम:	:	
2	**Name of organization** संस्था का नाम:	:	
3	**Introduction** परिचय	:	
4	**Purpose of research** शोध का उद्देश्य	:	
5	**Voluntary participation** स्वैच्छिक भागीदारी	:	
6	**Procedure** प्रक्रिया	:	
7	**Duration /** अवधि	:	
8	**Side effects /** दुष्प्रभाव	:	
9	**Risk /** जोखिम	:	
10	**Benefits /** लाभ	:	
11	**Confidentiality** गोपनीयता	:	
12	**Sharing the result /** परिणाम को साझा करना	:	
13	**Right to refuse or withdraw** मना करने या वापस लेने का अधिकार	:	
14	**Whom to contact /** संपर्क करने के लिए	:	